
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

SCHEDULE 14A

**PROXY STATEMENT PURSUANT TO SECTION 14(a) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

- Preliminary Proxy Statement
- Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
- Definitive Proxy Statement
- Definitive Additional Materials
- Soliciting Material under §240.14a-12

Tokai Pharmaceuticals, Inc.

(Name of the Registrant as Specified in its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

- No fee required.
- Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

Common Stock, \$0.001 par value per share ("Common Stock"), of Tokai Pharmaceuticals, Inc. ("Tokai")

(2) Aggregate number of securities to which transaction applies:

36,911,631 shares of Common Stock to be issued by Tokai pursuant to that certain Share Purchase Agreement, dated as of December 21, 2016, by and among Tokai, Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("Otic"), and the shareholders of Otic named therein.

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

The proposed maximum aggregate value of the transaction was calculated based on the product of 36,911,631 shares of Common Stock multiplied by \$1.00 per share (the average of the high and low trading prices of the Common Stock on The NASDAQ Global Market on January 20, 2017). In accordance with Section 14(g) of the Securities Exchange Act of 1933, as amended, the filing fee equals the product of 0.0001159 multiplied by the maximum aggregate value of the transaction.

(4) Proposed maximum aggregate value of transaction:

\$36,911,631

(5) Total fee paid:

\$4,279

Fee paid previously with preliminary materials.

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

PRELIMINARY PROXY STATEMENT—SUBJECT TO COMPLETION

DATED JANUARY 23, 2017



TOKAI PHARMACEUTICALS, INC.
255 State Street, 6th Floor
Boston, Massachusetts 02109
(617) 225-4305

, 2017

Dear Stockholder:

You are invited to attend a special meeting of the stockholders of Tokai Pharmaceuticals Inc., a Delaware corporation ("**Tokai**"), to be held on _____, 2017 at _____ local time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109.

As previously announced, on December 21, 2016, Tokai, Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("**Otic**"), and the shareholders of Otic named therein (each, a "**Seller**" and collectively, the "**Sellers**"), entered into a Share Purchase Agreement (the "**Share Purchase Agreement**"), pursuant to which, among other things, each Seller has agreed to sell to Tokai, and Tokai has agreed to purchase from each Seller, all of the ordinary and preferred shares of Otic (each an "**Otic Share**" and collectively, the "**Otic Shares**") in exchange for shares of Tokai common stock (the "**Otic Transaction**"), on the terms and subject to the conditions set forth in the Share Purchase Agreement. The Otic Transaction will result in a pharmaceutical company focused on the development and commercialization of products for ear, nose and throat ("**ENT**") disorders, including Otic's lead candidate which is a nasally-administered, combination drug product intended to address the underlying cause of otitis media and Eustachian tube dysfunction. As a result of the Otic Transaction, Otic will become a wholly owned subsidiary of Tokai and the Sellers are expected to own approximately 60% of the Tokai common stock.

In addition, Tokai has entered into a stock purchase agreement dated January _____, 2017 with Otic and certain purchasers set forth therein pursuant to which the purchasers have agreed to purchase _____ shares of Tokai common stock at a price of \$ _____ per share (the "**Tokai Stock Purchase Agreement**"). The Tokai Stock Purchase Agreement provides that the purchase and sale of the Tokai common stock will occur immediately following the closing of the Otic Transaction.

Shares of Tokai common stock are currently listed on The NASDAQ Global Market ("**NASDAQ**") under the symbol "TKAI." Tokai, in coordination with Otic, intends to file an initial listing application for the combined company with The NASDAQ Stock Market LLC pursuant to NASDAQ Listing Rules 1017 and 5110. After completion of the Otic Transaction, Tokai will be renamed "OticPharma, Inc." and expects to trade on The NASDAQ Global Market under the symbol "AOME." On _____, 2017, the last trading day before the date of this proxy statement, the closing sale price of Tokai common stock was \$ _____ per share.

Tokai is holding a special meeting of its stockholders in order to obtain the stockholder approvals necessary to complete the Otic Transaction and related matters. At the Tokai special meeting, Tokai will ask its stockholders to approve the issuances of Tokai common stock pursuant to the Share Purchase Agreement and pursuant to the related Tokai Stock Purchase Agreement; approve an amendment to Tokai's Amended and Restated Certificate of Incorporation effecting a reverse stock split of outstanding Tokai common stock at a ratio

[Table of Contents](#)

ranging from :1 to :1 as determined by the Tokai board of directors and agreed to by Otic; and approve the adjournment of the special meeting by Tokai’s board of directors, in its discretion, if necessary or appropriate, to solicit additional proxies to approve the other proposals, each as described in the accompanying proxy statement.

As described in the accompanying proxy statement, certain stockholders, directors and officers of Tokai, who hold in the aggregate approximately 36.3% of the outstanding common stock of Tokai (collectively, the “*Designated Tokai Equityholders*”), have entered into a support agreement with Otic (the “*Support Agreement*”). The Support Agreement places certain restrictions on the transfer of Tokai common stock held by the Designated Tokai Equityholders and includes an agreement to vote in favor of the issuance of Tokai common stock in the Otic Transaction and against any “acquisition proposal.”

After careful consideration and consultation with its financial advisor and outside legal counsel, the Tokai board of directors unanimously determined that the Otic Transaction, on the terms and subject to the conditions set forth in the Share Purchase Agreement, is fair to, and in the best interests of, Tokai and its stockholders and unanimously approved and declared advisable the Share Purchase Agreement, the issuance of Tokai common stock to the Sellers pursuant to the Share Purchase Agreement and the other transactions contemplated by the Share Purchase Agreement in accordance with the requirements of Delaware law.

The Tokai board of directors unanimously recommends that you vote “FOR” the approval of the issuances of Tokai common stock pursuant to the Share Purchase Agreement and pursuant to the related Tokai Stock Purchase Agreement and “FOR” each of the other proposals described in more detail in the accompanying proxy statement.

Your vote is important. It is important that your shares be represented and voted whether or not you plan to attend the special meeting in person. Whether or not you plan to attend the special meeting in person, we encourage you to read this proxy statement and submit your proxy or voting instructions as soon as possible. Please review the instructions on each of your voting options described in the proxy statement.

Sincerely,

Jodie P. Morrison
President and Chief Executive Officer

The accompanying proxy statement is dated , 2017 and is first being mailed to stockholders on or about , 2017.

TOKAI PHARMACEUTICALS, INC.

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS

TO BE HELD ON _____, 2017

To the Stockholders of Tokai Pharmaceuticals, Inc.:

You are cordially invited to attend a special meeting of stockholders of Tokai Pharmaceuticals, Inc. to be held on _____, 2017 at 9:00 a.m., Eastern Time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109. At the special meeting, stockholders will consider and vote on the following matters:

1. To approve the issuances of shares of common stock of Tokai, par value \$0.001 per share ("*Tokai common stock*"), pursuant to (i) the terms of the Share Purchase Agreement, dated as of December 21, 2016 (the "*Share Purchase Agreement*"), by and among Tokai, Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("*Otic*"), and the shareholders of Otic named therein (each a "*Seller*" and collectively, the "*Sellers*") (the "*Otic Transaction*") and (ii) the terms of the Tokai Stock Purchase Agreement, dated as of January _____, 2017 (the "*Tokai Stock Purchase Agreement*"), by and among Tokai, Otic, and the purchasers set forth therein (the "*Purchasers*") (the issuance pursuant to the Tokai Stock Purchase Agreement herein referred to as the "*Equity Financing*") (such proposal, the "*Share Issuances Proposal*"). A copy of the Share Purchase Agreement is attached as *Annex A* to the accompanying proxy statement and a copy of the form of Tokai Stock Purchase Agreement is attached as *Annex B* to the accompanying proxy statement;
2. To approve and adopt an amendment to Tokai's Amended and Restated Certificate of Incorporation to effect a reverse stock split of Tokai common stock, at a ratio ranging from _____:1 to _____:1, as determined by the Tokai board of directors and agreed to by Otic, as more fully set forth in the accompanying proxy statement (the "*Reverse Stock Split Proposal*"). A copy of the form of amendment to Tokai's Amended and Restated Certificate of Incorporation to effect the reverse stock split is attached as *Annex C* to the accompanying proxy statement;
3. To adjourn the special meeting to solicit additional votes to approve the Share Issuances Proposal or the Reverse Stock Split Proposal, if necessary or appropriate (the "*Adjournment Proposal*"); and
4. Any other business that may properly come before the special meeting and any adjournments or postponements thereof.

The accompanying proxy statement and its annexes more fully describe these items of business. Tokai urges you to read this information carefully.

The Tokai board of directors unanimously recommends that you vote "FOR" the Share Issuances Proposal and "FOR" each of the other proposals described in more detail in the accompanying proxy statement.

Each of the Share Issuances Proposal, Reverse Stock Split Proposal and Adjournment Proposal is an independent proposal, and none is conditioned upon the approval of any other proposal. The approval of the Share Issuances Proposal is required to consummate the Otic Transaction. The Otic Transaction may be consummated regardless of whether the Tokai stockholders approve or do not approve the Reverse Stock Split Proposal or the Adjournment Proposal. If the Share Issuances Proposal is not approved and the Otic Transaction is not consummated, Tokai's board of directors may still determine to proceed with the reverse stock split if the Reverse Stock Split Proposal is approved.

[Table of Contents](#)

Only stockholders of record of shares of Tokai common stock at the close of business on _____, 2017, the record date for the special meeting, are entitled to notice of and to vote at the special meeting and any adjournments or postponements of the special meeting. If you have any questions concerning the Otic Transaction, the related Equity Financing, the proposed reverse stock split, the special meeting or the accompanying proxy statement, need help voting your shares of Tokai common stock, or would like additional copies, without charge, of the enclosed proxy statement or proxy card, please contact Tokai Pharmaceuticals, Inc., 255 State Street, 6th Floor, Boston, Massachusetts 02109, Attention: Investor Relations, telephone: (617) 225-4305.

Please review in detail the attached proxy statement for a more complete statement regarding each of the Share Issuances Proposal, the Reverse Stock Split Proposal and the Adjournment Proposal, including descriptions of the Share Purchase Agreement and Tokai Stock Purchase Agreement, the background of the decision to enter into the Otic Transaction, the reasons that our board of directors has decided to recommend that you approve each of the Share Issuances Proposal, the Reverse Stock Split Proposal and the Adjournment Proposal and the section beginning on page 29 entitled "*Risk Factors*," describing certain risk factors relating to the Otic Transaction. Because of the significance of the Otic Transaction, your participation in the special meeting, in person or by proxy, is especially important. We hope that you will be able to attend the special meeting.

By Order of the Board of Directors,

Jodie P. Morrison
President and Chief Executive Officer

Boston, Massachusetts
Dated: _____, 2017

YOU MAY OBTAIN ADMISSION TO THE SPECIAL MEETING BY IDENTIFYING YOURSELF AT THE SPECIAL MEETING AS A STOCKHOLDER AS OF THE RECORD DATE. IF YOU ARE A RECORD OWNER, POSSESSION OF A COPY OF A PROXY CARD WILL BE ADEQUATE IDENTIFICATION. IF YOU ARE A BENEFICIAL (BUT NOT RECORD) OWNER, A COPY OF AN ACCOUNT STATEMENT FROM YOUR BANK, BROKER OR OTHER NOMINEE SHOWING SHARES HELD FOR YOUR BENEFIT ON _____, 2017 WILL BE ADEQUATE IDENTIFICATION.

WHETHER OR NOT YOU EXPECT TO ATTEND THE SPECIAL MEETING, IF YOU ARE A RECORD OWNER PLEASE COMPLETE, DATE AND SIGN THE ENCLOSED PROXY CARD AND MAIL IT PROMPTLY IN THE ENCLOSED ENVELOPE IN ORDER TO HELP ENSURE REPRESENTATION OF YOUR SHARES AT THE SPECIAL MEETING. NO POSTAGE NEED BE AFFIXED IF THE PROXY CARD IS MAILED IN THE UNITED STATES. ALTERNATIVELY, YOU MAY SUBMIT YOUR VOTE VIA THE INTERNET OR BY TELEPHONE BY FOLLOWING THE INSTRUCTIONS SET FORTH ON THE ENCLOSED PROXY CARD.

These transactions have not been approved or disapproved by the Securities and Exchange Commission (the "SEC"), and the SEC has not passed upon the fairness or merits of these transactions nor upon the accuracy or adequacy of the information contained in this proxy statement. Any representation to the contrary is unlawful.

[Table of Contents](#)

Table of Contents

	<u>Page</u>
SUMMARY	1
The Parties Involved in the Transaction	1
The Transaction Structure	2
Effect of the Otic Transaction on Otic Share Options, Otic Warrants and Tokai Stock Options	3
Expected Timing of the Otic Transaction	3
Tokai Board Recommendations and Reasons for the Otic Transaction	3
Opinion of Tokai’s Financial Advisor	4
The Tokai Special Meeting	5
Market Price and Dividend Information	5
No Solicitation; Third Party Competing Proposals	5
Changes to Board Recommendation	5
Conditions to Consummation of the Otic Transaction	6
Termination of the Share Purchase Agreement	6
Termination Fee and Expenses	6
Support Agreement	8
Interests of Tokai’s Directors and Executive Officers	8
Executive Officers and Directors Following the Otic Transaction	8
Regulatory Approvals	9
Material U.S. Federal Income Tax Consequences of the Transaction to Tokai Stockholders	9
Risk Factors	9
NASDAQ Global Market Listing	9
Anticipated Accounting Treatment	9
No Appraisal Rights	10
Equity Financing	10
Reverse Stock Split	10
QUESTIONS AND ANSWERS ABOUT THE SPECIAL MEETING AND THE OTIC TRANSACTION	11
SELECTED HISTORICAL AND UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION	17
Selected Historical Consolidated Financial Data of Tokai	17
Selected Historical Consolidated Financial Data of Otic	19
Selected Unaudited Pro Forma Combined Financial Data of Tokai and Otic	20
Comparative Historical and Unaudited Pro Forma Per Share Data	22

Table of Contents

	<u>Page</u>
<u>DESCRIPTION OF TOKAI COMMON STOCK</u>	24
<u>Common Stock</u>	24
<u>Preferred Stock</u>	25
<u>Stock Options</u>	25
<u>Provisions of Tokai’s Certificate of Incorporation and By-laws and Delaware Law That May Have Anti-Takeover Effects</u>	25
<u>NASDAQ Global Market Listing</u>	27
<u>MARKET PRICE AND DIVIDEND INFORMATION</u>	28
<u>Market Price of Tokai Common Stock</u>	28
<u>Dividends</u>	28
<u>RISK FACTORS</u>	29
<u>Risks Related to the Otic Transaction</u>	29
<u>Risks Related to the Otic Business</u>	34
<u>Risks Related to the Combined Company</u>	54
<u>Risks Related to the Proposed Reverse Stock Split</u>	62
<u>CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION</u>	64
<u>INFORMATION ABOUT THE SPECIAL MEETING</u>	65
<u>General</u>	65
<u>Date, Time and Place</u>	65
<u>Purposes of the Tokai Special Meeting</u>	65
<u>Recommendation of the Tokai Board of Directors</u>	65
<u>Stockholders Entitled to Vote; Record Date</u>	66
<u>Quorum and Broker Non-Votes</u>	66
<u>Required Vote</u>	66
<u>Voting by Stockholders</u>	67
<u>Revocation of Proxies</u>	68
<u>Voting by Tokai’s Directors, Executive Officers and Certain Stockholders</u>	68
<u>Solicitation of Proxies</u>	68
<u>No Appraisal Rights</u>	69
<u>Householding</u>	69
<u>Tabulation of Votes</u>	69
<u>Adjournments and Postponements</u>	69
<u>Attending the Special Meeting</u>	69
<u>THE OTIC TRANSACTION</u>	70
<u>The Transaction Structure</u>	70

Table of Contents

	<u>Page</u>
<u>Consideration</u>	70
<u>Effect of the Otic Transaction on Otic Share Options, Otic Warrants and Tokai Stock Options</u>	70
<u>Expected Timing of the Otic Transaction</u>	71
<u>Background of the Otic Transaction</u>	71
<u>Recommendation of the Tokai Board of Directors</u>	81
<u>Reasons for the Otic Transaction</u>	81
<u>Interests of Tokai’s Directors and Executive Officers</u>	83
<u>Opinion of Tokai’s Financial Advisor</u>	86
<u>Material U.S. Federal Income Tax Consequences of the Transaction to Tokai Stockholders</u>	95
<u>Regulatory Approvals</u>	95
<u>Anticipated Accounting Treatment</u>	95
<u>No Appraisal Rights</u>	96
<u>TERMS OF THE SHARE PURCHASE AGREEMENT</u>	97
<u>Explanatory Note Regarding the Share Purchase Agreement</u>	97
<u>The Otic Transaction Structure</u>	97
<u>Consideration</u>	98
<u>Exchange Ratio</u>	98
<u>Effect of the Otic Transaction on Otic Share Options, Otic Warrants and Tokai Stock Options</u>	98
<u>Directors and Officers of Tokai Following the Otic Transaction</u>	99
<u>Conditions to the Consummation of the Otic Transaction</u>	99
<u>Representations and Warranties</u>	101
<u>No Solicitation; Third Party Competing Proposal</u>	101
<u>Changes to Board Recommendation</u>	103
<u>Meeting of Tokai Stockholders</u>	104
<u>Covenants; Conduct of the Businesses</u>	104
<u>Indemnification and Insurance</u>	108
<u>Other Agreements</u>	109
<u>Lock-up Agreements</u>	110
<u>Termination of the Share Purchase Agreement</u>	110
<u>Termination Fee and Expenses</u>	112
<u>Regulatory Approvals</u>	113
<u>Amendments and Waivers</u>	113
<u>Specific Performance</u>	113
<u>Third Party Beneficiaries</u>	114

Table of Contents

	<u>Page</u>
<u>AGREEMENTS RELATED TO THE SHARE PURCHASE AGREEMENT</u>	115
<u>Support Agreement</u>	115
<u>Tokai Stock Purchase Agreement</u>	115
<u>Registration Rights Agreement</u>	115
<u>SHARE ISSUANCES PROPOSAL</u>	117
<u>REVERSE STOCK SPLIT PROPOSAL</u>	118
<u>Purpose</u>	119
<u>NASDAQ Listing Requirements</u>	119
<u>Principal Effects of the Reverse Stock Split</u>	119
<u>Risks of the Reverse Stock Split</u>	120
<u>Procedure for Effecting Reverse Stock Split and Exchange of Stock Certificates</u>	120
<u>Fractional Shares</u>	121
<u>Material U.S. Federal Income Tax Consequences of the Reverse Stock Split</u>	121
<u>Vote Required; Recommendation of the Tokai Board of Directors</u>	124
<u>ADJOURNMENT PROPOSAL</u>	125
<u>TOKAI'S BUSINESS</u>	126
<u>OTIC'S BUSINESS</u>	127
<u>TOKAI'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	138
<u>Overview</u>	138
<u>Financial Operations Overview</u>	139
<u>Critical Accounting Policies and Significant Judgments and Estimates</u>	141
<u>JOBS Act</u>	143
<u>Results of Operations</u>	143
<u>Liquidity and Capital Resources</u>	148
<u>Contractual Obligations and Commitments</u>	152
<u>Off-Balance Sheet Arrangements</u>	152
<u>Recently Issued Accounting Pronouncements</u>	152
<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT TOKAI'S MARKET RISK</u>	153
<u>OTIC'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	154
<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT OTIC'S MARKET RISK</u>	164
<u>Interest Rate Risk</u>	164
<u>Foreign Exchange Rate Risk</u>	164
<u>Effects of Inflation</u>	164

[Table of Contents](#)

	<u>Page</u>
EXECUTIVE OFFICERS AND DIRECTORS FOLLOWING THE OTIC TRANSACTION	165
Executive Officers and Directors	165
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT OF TOKAI	169
UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION	171
WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION BY REFERENCE	182
OTHER MATTERS	184
Stockholder Proposals	184
Communication with the Tokai Board of Directors	184
INDEX TO TOKAI CONSOLIDATED FINANCIAL STATEMENTS	F-1
INDEX TO OTIC CONSOLIDATED FINANCIAL STATEMENTS	F-39
ANNEX A: SHARE PURCHASE AGREEMENT	
ANNEX B: FORM OF TOKAI STOCK PURCHASE AGREEMENT	
ANNEX C: FORM OF CERTIFICATE OF AMENDMENT OF RESTATED CERTIFICATE OF INCORPORATION OF TOKAI PHARMACEUTICALS, INC. (REGARDING THE REVERSE STOCK SPLIT)	
ANNEX D: OPINION OF WEDBUSH SECURITIES INC.	

SUMMARY

This summary, together with the section of this proxy statement entitled “Questions and Answers About the Special Meeting and the Otic Transaction,” highlights selected information from this proxy statement and may not contain all of the information that is important to you as a stockholder of Tokai or that you should consider before voting on the proposals being considered at the special meeting. To better understand the Otic Transaction and the related Equity Financing, you should read carefully this entire proxy statement and all of its annexes, including the Share Purchase Agreement, which is attached as Annex A, and the Tokai Stock Purchase Agreement, a form of which is attached as Annex B, before voting on the proposals being considered at the special meeting. This summary includes page references directing you to more complete descriptions. For more information, please see the section entitled “Where You Can Find More Information; Incorporation by Reference,” beginning on page 182 of this proxy statement.

The Parties Involved in the Transaction

Tokai Pharmaceuticals, Inc.

Tokai Pharmaceuticals, Inc. (“*Tokai*”) is a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases. Tokai has focused substantially all of its research and development efforts on the development of galeterone, an oral small molecule, including clinical trials of galeterone for the treatment of patients with metastatic castration-resistant prostate cancer (“*mCRPC*”). Tokai also has a drug discovery program, known as ARDA (androgen receptor degradation agents), under which it was seeking to identify and develop novel compounds for patients with androgen receptor signaling diseases, including prostate cancer, either alone or in combination with other products.

In July 2016, Tokai announced its plan to discontinue ARMOR3-SV, its pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant, following the recommendation made by the trial’s independent data monitoring committee in July 2016. In addition, in August 2016, Tokai determined to discontinue enrollment in its Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi® (enzalutamide) and not to proceed with its planned clinical trials of galeterone. Only patients in the ARMOR2 trial are continuing treatment at this time.

In September 2016, Tokai completed a workforce reduction, which was designed to reduce its operating expenses while it conducted a review of development options for galeterone and its ARDA program.

For more information on Tokai’s business, see the section entitled “*Tokai’s Business*,” beginning on page 126 of this proxy statement.

Otic Pharma, Ltd.

Otic Pharma, Ltd. (“*Otic*”) is a clinical-stage, specialty pharmaceutical company focused on the acquisition and development of products for disorders of the ear, nose, and throat (“*ENT*”). The company has two novel technologies that are initially being developed for conditions of the ear.

OP-01 is a foam-based technology. It was developed by Otic with the intent to be used as a delivery vehicle for drugs which are to be placed into the ears, as well as the nasal and sinus cavities. OP-01 is currently being developed as an improved treatment option for acute otitis externa (“*AOE*” or “swimmers ear”), a common medical condition of the outer ear canal that globally affects tens of millions of adults and children every year.

[Table of Contents](#)

Otic has completed four clinical trials of OP-01 in 353 subjects, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP-01 that performed similarly to standard of care. Otic is now planning to further modify the formulation of OP-01 to create a clinically differentiated, best-in-class product for AOE that is an improvement to the standard of care.

OP-02 is a surfactant-based technology. It was originally developed by Otodyne, Inc. and subsequently licensed to Otic in November 2015. OP-02 is currently being developed as a potential first-in-class treatment option for patients with otitis media (“**OM**”) and Eustachian tube dysfunction (“**ETD**”). OM and ETD are common medical conditions of the middle ear that globally affect more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice and is the most frequent reason children are prescribed antibiotics and undergo surgery. OP-02 is a daily nasal spray, designed to improve and maintain the Eustachian tube’s ability to drain and ventilate the middle ear. Otic is planning to initiate multiple phase 1 clinical studies of OP-02 in 2017 to explore the safety and tolerability of OP-02, as well as explore how OP-02 affects Eustachian tube function (pharmacodynamics). These phase 1 studies will evaluate single and repeated intranasal doses of OP-02 in adults. Upon completion of these studies, Otic expects that its initial phase 2 studies of OP-02 will focus on prevention of acute, recurrent, and chronic OM in children.

For more information on Otic’s business, see the section entitled “*Otic’s Business*,” beginning on page 127 of this proxy statement.

The Transaction Structure (pages 70, 97)

Upon the terms and subject to the conditions set forth in the Share Purchase Agreement, dated as of December 21, 2016 (the “**Share Purchase Agreement**”), by and among Tokai, Otic and the shareholders of Otic (each a “**Seller**” and collectively, the “**Sellers**”), Tokai will acquire all of the ordinary and preferred shares of Otic in exchange for the issuance to the Sellers of a specified number of shares of Tokai common stock and to assume all outstanding share options and warrants of Otic. Following the Otic Transaction, Otic will be a wholly owned subsidiary of Tokai.

Based on the outstanding share capital of Otic as of the date of the Share Purchase Agreement and the shares issuable upon exercise of warrants to purchase shares of Otic and the conversion of certain outstanding debt facilities of Otic into shares of Otic that are expected to be exercised or converted prior to the closing of the Otic Transaction, Tokai expects to issue _____ shares of Tokai common stock in the Otic Transaction. If all of Otic’s outstanding options and warrants are exercised prior to closing, Tokai will issue a total of 36,911,631 shares of Tokai common stock in the Otic Transaction. Following the closing of the Otic Transaction, the shareholders of Otic are expected to hold approximately 60% of the outstanding shares of Tokai common stock, excluding for this purpose the effect on ownership of the issuance of shares in the Equity Financing. The relative percentage ownership of the combined company was derived using a stipulated value of Otic of approximately \$50.0 million and of Tokai of approximately \$33.0 million.

The issuance of Tokai common stock to the Sellers will be issued in transactions exempt from registration under the Securities Act of 1933, as amended (the “**Securities Act**”) in reliance on Section 4(a)(2) of the Securities Act and Regulation D or Regulation S promulgated thereunder and may not be offered or sold by the holders of those shares absent registration or an applicable exemption from registration requirements.

Effect of the Otic Transaction on Otic Share Options, Otic Warrants and Tokai Stock Options
(pages 70-71, 98-99)

Otic Share Options and Otic Warrants

Pursuant to the Share Purchase Agreement, at closing Tokai will assume the outstanding share option awards and warrants of Otic (other than warrants of Otic that are exercised in connection with the Otic Transaction). Each of these options and warrants will be adjusted to reflect a ratio of shares of Tokai common stock for each Otic share. Accordingly, at closing, each of Otic's outstanding share option awards and warrants will become exercisable, as the case may be, for or into shares of Tokai common stock for each Otic share it was previously exercisable for, at a correspondingly adjusted exercise price, provided that the exercise price of such stock options and warrants will be rounded down to the nearest whole share and the exercise prices will be rounded up to the nearest cent, and no cash payment will be made in respect of such rounding. After giving effect to the ratio, and assuming no exercise of, or other change in the number of, outstanding share option awards and warrants of Otic from the date of the Share Purchase Agreement, Tokai will assume options to purchase shares of Tokai common stock at a weighted average exercise price of \$ per share and warrants to purchase shares of Tokai common stock at a weighted average exercise price of \$ per share. If all of these options and warrants were exercised prior to the closing of the Otic Transaction, Tokai would issue 36,911,631 shares of common stock and the Otic shareholders would own approximately 62% of the outstanding shares of Tokai common stock.

Tokai Options

Upon closing of the Otic Transaction, all of Tokai's outstanding stock options will remain outstanding and in effect. Tokai's board of directors has determined that the Otic Transaction constitutes a change in control for purposes of Tokai's stock options. As a result, if any holder of Tokai stock options (other than Tokai's non-employee directors) is terminated without cause or resigns for good reason following the closing, such holder's stock options will immediately vest in full. Stock options held by Tokai's non-employee directors will vest in full immediately upon closing.

Expected Timing of the Otic Transaction
(page 71)

Unless the Share Purchase Agreement is earlier terminated pursuant to its terms, the Otic Transaction will be consummated as promptly as practicable, but in no event later than the second business day following the satisfaction or waiver of the conditions to closing, or as Tokai and Otic agree. However, because the Otic Transaction is subject to a number of conditions to closing, neither Tokai nor Otic can predict exactly when the closing will occur or if it will occur at all.

Tokai Board Recommendation and Reasons for the Otic Transaction
(pages 65-66, 81-83, 103-104, 117, 124-125)

The Tokai board of directors has determined and believes that each of the proposals to be voted on at the special meeting is fair to, advisable, and in the best interests of Tokai and its stockholders and has approved such items. The Tokai board of directors recommends that Tokai stockholders vote "FOR" each of the proposals to be voted on. For more information on the Tokai board of directors' recommendation see the section entitled "*Information About the Special Meeting—Recommendation of the Tokai Board of Directors*," beginning on page 65 of this proxy statement, and the section entitled "*Terms of the Share Purchase Agreement—Changes to Board Recommendation*," beginning on page 103 of this proxy statement.

[Table of Contents](#)

In reaching its unanimous decision to approve the Share Purchase Agreement and the issuance of Tokai common stock pursuant to the Share Purchase Agreement, the Tokai board of directors considered a number of factors, including, among others, the following:

- that Otic's portfolio of products for ENT disorders, including Otic's lead candidate, which is a nasally-administered, combination drug product (OP-02) intended to address the underlying cause of otitis media and Eustachian tube dysfunction (OM/ETD), represents a meaningful market opportunity, and may provide new medical benefits for patients;
- that the Otic Transaction would provide existing Tokai stockholders with the opportunity to participate in the potential growth of the combined company following the transaction; and
- that Tokai had discontinued its pivotal Phase 3 clinical trial of galeterone following the recommendation made by the trial's independent data monitoring committee and has discontinued enrollment in its Phase 2 clinical trial of galeterone.

For more information on the Tokai board of directors' reasons for approving the Otic Transaction, see the section entitled "*The Otic Transaction—Reasons for the Otic Transaction*," beginning on page 81 of this proxy statement.

**Opinion of Tokai's Financial Advisor
(pages 86-95)**

The Tokai board of directors engaged Wedbush Securities Inc. ("*Wedbush*") to provide financial advisory and investment banking services and to consider and evaluate potential strategic transactions, and ultimately requested that Wedbush render an opinion as to whether the ratio of shares of Tokai common stock issued for the Otic share capital (as described more fully in the section entitled "*Terms of the Share Purchase Agreement—Exchange Ratio*," beginning on page 98 of this proxy statement, the "*exchange ratio*") in connection with the Otic Transaction was fair to the stockholders of Tokai from a financial point of view. At the December 21, 2016 meeting of the Tokai board of directors, Wedbush rendered its oral opinion, subsequently confirmed by delivery of a written opinion dated December 21, 2016, to the Tokai board of directors that, as of the date of such opinion, and based upon the assumptions made, procedures followed, matters considered, and qualifications and limitations of the review set forth in its written opinion, the exchange ratio was fair to the stockholders of Tokai from a financial point of view.

The full text of Wedbush's written opinion, which sets forth the procedures followed, assumptions made, matters considered, and limitations and qualifications of the review undertaken in connection with the opinion, is attached as Annex D. Wedbush's opinion was intended for the use and benefit of the Tokai board of directors (in its capacity as such) in connection with its evaluation of the Otic Transaction. Wedbush's opinion was not intended to be used for any other purpose without Wedbush's prior written consent in each instance, except as Tokai's counsel advises is required by law. Wedbush has consented to the use of Wedbush's opinion in this proxy statement. Wedbush's opinion does not address Tokai's underlying business decision to enter into the Share Purchase Agreement or complete the Otic Transaction, the relative merits of the Otic Transaction compared to any alternative transactions or strategies that were or may be available to Tokai and the other proposals to be addressed at the special meeting. Wedbush's opinion did not constitute a recommendation to the Tokai board of directors as to how to act or to any Tokai stockholder or any other person as to how to vote with respect to the Otic Transaction or any other matter (including, without limitation, the amount of consideration to be paid).

**The Tokai Special Meeting
(pages 11-16, 65-69)**

Tokai will hold a special meeting of the Tokai stockholders on _____, 2017, at _____ local time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109 to vote on the issuance of Tokai common stock in the Otic Transaction and the related issuance of Tokai common stock in the Equity Financing and other related actions, including the proposed reverse stock split.

**Market Price and Dividend Information
(page 28)**

Tokai's common stock trades under the symbol "TKAI" on The NASDAQ Global Market and has been publicly traded since September 17, 2014. On December 21, 2016, the last trading day prior to the Tokai board of directors' approval of the Otic Transaction, the reported closing price of the Tokai common stock was \$1.01 per share. On _____, 2017, the latest practicable trading date before the filing of this proxy statement, the reported closing price of the Tokai common stock was \$ _____ per share. Because the price of Tokai common stock is subject to fluctuation, the market value of the shares of Tokai common stock that Otic shareholders will be entitled to receive pursuant to the terms of the Share Purchase Agreement may increase or decrease.

Neither Tokai nor Otic has ever declared or paid cash dividends on its capital stock. Any determination to pay dividends following consummation of the Otic Transaction or otherwise will be at the discretion of Tokai's then-current board of directors and will depend upon a number of factors, including its results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors Tokai's then-current board of directors deems relevant.

**No Solicitation; Third Party Competing Proposals
(pages 101-103)**

Under the Share Purchase Agreement, both Tokai and Otic are subject to customary covenants restricting the solicitation of competing offers. However, subject to certain requirements set forth in the Share Purchase Agreement, Tokai is entitled to furnish non-public information to, and engage in discussions or negotiations with, third parties who submit a bona fide, unsolicited written proposal to acquire 50% or more of the equity securities or consolidated total assets of Tokai, so long as the Tokai board of directors determines in its good faith judgment that such acquisition proposal is more favorable to the holders of Tokai's capital stock than the transactions contemplated by the Share Purchase Agreement (after consultation with its financial and legal advisors) and which Tokai's board of directors determines to be reasonably capable of being completed on the terms proposed.

**Changes to Board Recommendation
(pages 103-104)**

Prior to Tokai stockholder approval of the Share Purchase Agreement and the issuance of Tokai common stock to the Sellers pursuant to the Share Purchase Agreement, the Tokai board of directors is permitted to withhold, withdraw or modify, or publicly propose to withdraw or modify, its approval or recommendation that Tokai stockholders vote in favor of the Share Issuances Proposal if the Tokai board of directors determines in good faith (after consultation with outside legal counsel) that the failure to do so could reasonably be expected to be inconsistent with its fiduciary obligations under applicable law.

Conditions to Consummation of the Otic Transaction
(pages 99-101)

The Share Purchase Agreement sets forth certain conditions to the obligations of the parties in the transaction, including:

- Tokai stockholders approving the Share Issuances Proposal;
- the filing, obtainment or occurrence of all authorizations and consents, including Israeli tax rulings described in the Share Purchase Agreement;
- the absence of any order, executive order, stay, decree, judgment or injunction (preliminary or permanent) or statute, rule, or regulation prohibiting consummation of the Otic Transaction;
- the approval of an initial listing application on The NASDAQ Global Market with respect to the shares of Tokai common stock to be issued in the Otic Transaction;
- the accuracy of representations and warranties, subject to customary materiality standards;
- the performance of covenants in all material respects;
- the absence of any continuing Tokai or Otic material adverse effect; and
- resignations of the directors of Tokai who will not continue to serve as directors following closing of the Otic Transaction pursuant to the terms of the Share Purchase Agreement.

Termination of the Share Purchase Agreement
(pages 110-111)

The Share Purchase Agreement includes certain termination rights, including:

- by either Tokai or Otic upon mutual written consent;
- by either Tokai or Otic, if the Otic Transaction is not consummated by April 30, 2017;
- by either Tokai or Otic, if a final non-appealable governmental order is issued permanently restraining or prohibiting the Otic Transaction;
- by either Tokai or Otic, if Tokai's stockholders fail to approve the Otic Transaction at the special meeting of Tokai stockholders;
- by either Tokai or Otic, if there is a breach such that the applicable accuracy of representations condition cannot be satisfied;
- by Tokai, if Otic has knowingly and materially breached its non-solicitation obligations;
- by Tokai, if Tokai complies with its non-solicitation obligations in order to accept a superior proposal and pays to Otic the Tokai termination fee; and
- by Otic, if certain triggering events occur, such as a change of the Tokai board of directors' recommendation that the Tokai or Otic stockholders vote "FOR" the Share Issuances Proposal, breach of Tokai's non-solicitation covenants, or approval by the Tokai board of directors of a competing proposal.

Termination Fee and Expenses
(pages 112-113)

Under the terms of the Share Purchase Agreement, all fees and expenses incurred in connection with the Share Purchase Agreement are to be paid by the party incurring such expenses, regardless of whether the Otic Transaction is consummated.

However, Otic must pay Tokai a termination fee of \$1.5 million if:

- Tokai has terminated the Share Purchase Agreement as a result of a knowing and material breach by Otic of its non-solicitation obligations in the Share Purchase Agreement; or
- Tokai has terminated the Share Purchase Agreement as a result of a material breach or failure to perform by Otic of any representation, warranty, covenant or agreement set forth in the Share Purchase Agreement, which breach has caused a closing condition in the Share Purchase Agreement not to be satisfied and remains uncured by Otic prior to the earlier of the Outside Date and the expiration of a 30-day period commencing upon delivery of written notice from Tokai to Otic of such breach.

Tokai must pay Otic a termination fee of \$1.0 million (the "*Tokai termination fee*") if:

- Tokai has terminated the Share Purchase Agreement at any time prior to the approval by Tokai's stockholders of the issuance of the shares of Tokai common stock in the Otic Transaction and each of the following has occurred: Tokai received a superior proposal (as such term is defined in the section entitled, "*Terms of the Share Purchase Agreement—No Solicitation; Third Party Competing Proposal*" in this proxy statement beginning on page 101); Tokai has complied in all material respects with its non-solicitation obligations in the Share Purchase Agreement in order to accept such superior proposal; and the Tokai board of directors approved, and Tokai concurrently with termination of the Share Purchase Agreement entered into, a definitive agreement with respect to such superior proposal;
- so long as prior to the termination of the Share Purchase Agreement, any person makes an acquisition proposal or amends an acquisition proposal made prior to the date of the Share Purchase Agreement with respect to Tokai and within 12 months after such termination Tokai enters into a definitive agreement to consummate, or consummates, any acquisition and:
 - either Otic or Tokai has terminated the Share Purchase Agreement and the Otic Transaction has not been consummated prior to the outside date; provided, such terminating party did not cause such failure to fulfill any obligation under the Share Purchase Agreement and was not a principal cause of or resulted in the failure of the Otic Transaction to so occur prior to the outside date; or
 - Otic has terminated the Share Purchase Agreement as a result of a material breach or failure to perform by Tokai of any representation, warranty, covenant or agreement set forth in the Share Purchase Agreement, which breach has caused a closing condition in the Share Purchase Agreement not to be satisfied and remains uncured by Tokai prior to the earlier of the Outside Date and the expiration of a 30-day period commencing upon delivery of written notice from Otic to Tokai of such breach; or
- Otic has terminated the Share Purchase Agreement at any time prior to the approval by Tokai's stockholders of the issuance of the shares of Tokai common stock in the Otic Transaction due to the occurrence of any of the following:
 - Tokai's board of directors failed to recommend that the stockholders of Tokai vote to approve the issuance of Tokai common stock in the Otic Transaction or withdrew or modified its recommendation;
 - Tokai's board of directors (or any committee thereof) approved or recommended to the Tokai stockholders an acquisition proposal;
 - a tender or exchange offer for outstanding shares of Tokai's common stock was commenced and Tokai's board of directors recommended that the Tokai stockholders tender or exchange

their shares in such offer or failed to recommend against such offer within ten business days of its commencement; or

- Tokai has knowingly and materially breached its no solicitation obligations in to the Share Purchase Agreement.

**Support Agreement
(page 115)**

Certain stockholders, directors and officers of Tokai, who as of December 31, 2016 collectively owned approximately 36.3% of outstanding Tokai common stock, have agreed to vote in favor of the issuance of Tokai common stock in the Otic Transaction and against any “acquisition proposal.”

**Interests of Tokai’s Directors and Executive Officers
(pages 83-86)**

In considering the recommendation of the Tokai board of directors with respect to the issuance of shares of Tokai common stock pursuant to the Share Purchase Agreement and the other matters to be voted upon by Tokai stockholders at the Tokai special meeting, Tokai stockholders should be aware that certain members of the Tokai board of directors and the executive officers of Tokai have interests in the Otic Transaction that may be different from, or in addition to, interests they have as Tokai stockholders, including:

- each of Tokai’s executive officers is party to an employment agreement that provides for severance benefits in the event of a qualifying termination of employment during the period of time commencing on the closing of the Otic Transaction and ending one year following the closing of the Otic Transaction;
- the stock option agreements evidencing the stock options held by each of Tokai’s executive officers provide that upon a qualifying termination of employment during the period of time commencing on the closing of the Otic Transaction and ending one year following the closing of the Otic Transaction, the stock options will vest in full;
- the stock option agreements evidencing the stock options held by each of Tokai’s non-employee directors provide that upon the closing of the Otic Transaction, the stock options will vest in full; and
- under the Share Purchase Agreement, Tokai’s directors and executive officers are entitled to continued indemnification, expense advancement and insurance coverage.

**Executive Officers and Directors Following the Otic Transaction
(pages 99, 165-168)**

Immediately following the completion of the Otic Transaction, the executive management team of the combined company is expected to be composed of the current executive team of Otic: Gregory J. Flesher, President and Chief Executive Officer; Christine G. Ocampo, Chief Financial and Compliance Officer; and Dr. Catherine C. Turkel, Chief Development Officer.

The combined company’s board of directors will initially be fixed at seven members, consisting of (i) four members designated by Otic: Keith A. Katkin as Chairman, Gregory J. Flesher, Gary A. Lyons and Erez Chimovits and (ii) three board members designated by Tokai, which may include existing board members and up to one new member designated by Tokai.

[Table of Contents](#)

Regulatory Approvals
(pages 95, 113)

Neither Tokai nor Otic is required to make any filings or to obtain approvals or clearances from any regulatory authorities in the United States or other countries to consummate the Otic Transaction contemplated by the Share Purchase Agreement. In Israel, Otic is required to prepare, file and receive all Israeli tax rulings with respect to the Otic Transaction, and Tokai is required to deliver to Otic an executed copy of an undertaking in the standard form required by the Office of the Chief Scientist (“OCS”) from non-Israeli residents investing in Israeli companies which have received support from the OCS. In the United States, Tokai must comply with applicable federal and state securities laws and NASDAQ rules and regulations in connection with the issuance of shares of Tokai common stock in the Otic Transaction and the related issuance of shares of Tokai common stock in the Equity Financing, including the filing with the SEC of this proxy statement.

Material U.S. Federal Income Tax Consequences of the Transaction to Tokai Stockholders
(page 95)

Neither the Otic Transaction nor the related Equity Financing will result in any taxable gain or loss for U.S. federal income tax purposes to any Tokai stockholder in his, her or its capacity as a Tokai stockholder.

Risk Factors
(pages 29-63)

The Otic Transaction involves a number of risks. In addition, both Tokai and Otic are subject to various risks associated with their businesses and their industries that will be implicated in the case of Tokai if the Otic Transaction is not consummated and in the case of Otic if the Otic Transaction is consummated. You should consider all the information contained in this proxy statement in deciding how to vote for the proposals presented in this proxy statement, including the possibility that the Otic Transaction may not be completed. These risks are discussed in greater detail under the section entitled “*Risk Factors*,” beginning on page 29 of this proxy statement. Tokai encourages you to read and consider all of these risks carefully.

NASDAQ Global Market Listing
(pages 27, 119)

The Share Purchase Agreement requires Tokai to use its commercially reasonable efforts to maintain its existing listing on NASDAQ, to obtain approval of the listing of the combined company on NASDAQ and to cause the shares of Tokai common stock being issued in the Otic Transaction to be approved for listing, subject to notice of issuance, on NASDAQ at or prior to the consummation of the Otic Transaction. Tokai, with cooperation from Otic, intends to file an initial listing application with NASDAQ, in satisfaction of Tokai’s obligations under the Share Purchase Agreement, and toward fulfillment of one of the conditions to the consummation of the Otic Transaction under the Share Purchase Agreement (which is more fully described in the section of this proxy statement entitled, “*Terms of the Share Purchase Agreement—Conditions to the Consummation of the Otic Transaction*”).

Anticipated Accounting Treatment
(pages 95-96)

Because Otic has been determined to be the accounting acquirer in the Otic Transaction, but not the legal acquirer, the Otic Transaction will be treated by Tokai as a reverse acquisition under the acquisition method of accounting in accordance with accounting principles generally accepted in the United States (“*GAAP*”). For accounting purposes, Otic is considered to be acquiring Tokai in the Otic Transaction.

[Table of Contents](#)

As a result, upon consummation of the Otic Transaction, (1) the historical financial statements of Otic will become the historical financial statements of the combined company and (2) Otic will record the business combination in its financial statements and will apply the acquisition method to account for the acquired assets and assumed liabilities of the Tokai as of the closing date of the transaction. Applying the acquisition method includes recording the identifiable assets acquired and liabilities assumed at their fair values, and recording goodwill for the excess of the purchase price over the aggregate fair value of the identifiable assets acquired and liabilities assumed, if any, or recording a bargain purchase gain if the aggregate fair value of the identifiable assets acquired and liabilities assumed exceeds the purchase price for the acquisition.

No Appraisal Rights
(pages 69, 96)

Holders of Tokai common stock will not be entitled to any dissenters' rights or appraisal rights with respect to any of the proposals to be voted on at the special meeting.

Equity Financing
(page 115)

In connection with the Otic Transaction, Tokai has entered into the Tokai Stock Purchase Agreement dated January _____, 2017 with Otic and certain purchasers set forth therein pursuant to which the purchasers have agreed to purchase _____ shares of Tokai common stock at a price of \$1.11 per share. The Tokai Stock Purchase Agreement provides that the purchase and sale of the Tokai common stock will occur immediately following the closing of the Otic Transaction.

Reverse Stock Split
(pages 118-124)

Under the Share Purchase Agreement, Tokai has agreed to seek stockholder approval of a reverse stock split with the specific terms to be proposed by Tokai and approved by Otic to the extent necessary in order to maintain Tokai's listing on NASDAQ. Based on information currently available to Tokai, Tokai anticipates that it will be unable to meet the \$4.00 minimum bid price initial listing requirement at the closing of the Otic Transaction unless it effects a reverse stock split.

**QUESTIONS AND ANSWERS ABOUT
THE SPECIAL MEETING AND THE OTIC TRANSACTION**

The following section provides answers to frequently asked questions about the Otic Transaction. This section, however, provides only summary information. For a more complete response to these questions and for additional information, please refer to the cross-referenced sections.

Q: When and where is the special meeting of the Tokai stockholders being held?

A: The special meeting will be held on _____, 2017 at _____ local time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109. For more information see the section entitled “*Information About the Special Meeting*,” beginning on page 65 of this proxy statement.

Q: Why did I receive these proxy materials?

A: Tokai’s board of directors has made these materials available to you in connection with the solicitation of proxies for use at its special meeting of stockholders to be held on _____, 2017. As a holder of common stock, you are invited to attend the special meeting and are requested to vote on the items of business described in this proxy statement. This proxy statement includes information that we are required to provide to you under SEC rules and that is designed to assist you in voting your shares. For more information see the section entitled “*Information About the Special Meeting*,” beginning on page 65 of this proxy statement.

Q: Who can vote at the special meeting?

A: To be entitled to vote, you must have been a stockholder of record at the close of business on _____, 2017, the record date for Tokai’s special meeting. There were _____ shares of our common stock outstanding and entitled to vote at the special meeting as of the record date.

Q: How many votes do I have?

A: Each share of Tokai common stock that you own as of the record date will entitle you to one vote on each matter considered at the special meeting.

Q: How do I vote?

A: If you are the “record holder” of your shares, meaning that your shares are registered in your name in the records of Tokai’s transfer agent, Continental Stock Transfer & Trust Company, you may vote your shares at the meeting in person or by proxy as follows:

1. **Over the Internet:** To vote over the Internet, please go to the following website: www.proxypush.com/tkai, and follow the instructions at that site for submitting your proxy electronically. If you vote over the Internet, you do not need to complete and mail your proxy card or vote your proxy by telephone. You must specify how you want your shares voted or your Internet vote cannot be completed, and you will receive an error message. You must submit your Internet proxy before 11:59 p.m., Eastern Time, on _____, 2017, the day before the special meeting, for your proxy to be valid and your vote to count.
2. **By Telephone:** To vote by telephone, please call (866) 206-4382 and follow the instructions provided on the proxy card. If you vote by telephone, you do not need to complete and mail your proxy card or vote your proxy over the Internet. You must specify how you want your shares voted and confirm your vote at the end of the call or your telephone vote cannot be completed. You must submit your telephonic proxy before 11:59 p.m., Eastern Time, on _____, 2017, the day before the special meeting, for your proxy to be valid and your vote to count.
3. **By Mail:** To vote by mail, you must mark, sign and date the proxy card and then mail the proxy card in accordance with the instructions on the proxy card. If you vote by mail, you do not need to

[Table of Contents](#)

vote your proxy over the Internet or by telephone. Mediant Communications, Inc. must receive the proxy card not later than _____, 2017, the day before the special meeting, for your proxy to be valid and your vote to count. If you return your proxy card but do not specify how you want your shares voted on any particular matter, they will be voted in accordance with the recommendations of our board of directors.

4. **In Person at the Meeting:** If you attend the special meeting, you may deliver your completed proxy card in person or you may vote by completing a ballot, which Tokai will provide to you at the meeting.

If your shares are held in “street name,” meaning they are held for your account by an intermediary, such as a broker, then you are deemed to be the beneficial owner of your shares and the broker that actually holds the shares for you is the record holder and is required to vote the shares it holds on your behalf according to your instructions. The proxy materials, as well as voting and revocation instructions, should have been forwarded to you by the broker that holds your shares. In order to vote your shares, you will need to follow the instructions that your broker provides you. Many brokers solicit voting instructions over the Internet or by telephone.

If you do not give instructions to your broker, your broker will not be able to vote your shares with respect to “non-discretionary” items. Each of the Share Issuances Proposal, the Reverse Stock Split Proposal and the Adjournment Proposal are “non-discretionary” items. Accordingly, if you do not give your broker voting instructions on any of these proposals, your broker may not vote your shares with respect to such matter and your shares will be counted as “broker non-votes” with respect to such proposal. A “broker non-vote” occurs when shares held by a broker are not voted with respect to a particular proposal because the broker does not have or did not exercise discretionary authority to vote on the matter and has not received voting instructions from its clients.

Regardless of whether your shares are held in street name, you are welcome to attend the meeting. You may not vote shares held in street name in person at the meeting, however, unless you obtain a legal proxy, executed in your favor, from the holder of record (i.e., your broker). A legal proxy is not the form of proxy included with this proxy statement.

Q: Can I change my vote?

A: If your shares are registered directly in your name, you may revoke your proxy and change your vote at any time before the vote is taken at the special meeting. To do so, you must do one of the following:

1. Vote over the Internet or by telephone as instructed above. Only your latest Internet or telephone vote is counted.
2. Sign and return a new proxy card. Only your latest dated and timely received proxy card will be counted.
3. Attend the special meeting and vote in person as instructed above. Attending the special meeting will not alone revoke your Internet vote, telephone vote or proxy card submitted by mail, as the case may be.
4. Give Tokai’s corporate secretary written notice before or at the meeting that you want to revoke your proxy.

If your shares are held in “street name,” you may submit new voting instructions by contacting your broker or other nominee. You may also vote in person at the special meeting if you obtain a legal proxy as described in the answer above.

Q: How many shares must be represented to have a quorum and hold the special meeting?

A: A majority of Tokai’s shares of common stock outstanding at the record date must be present in person or represented by proxy to hold the special meeting. This is called a quorum. For purposes of determining whether a quorum exists, Tokai counts as present any shares that are voted over the Internet, by telephone, by completing and submitting a proxy card by mail or that are represented in

[Table of Contents](#)

person at the meeting. Further, for purposes of establishing a quorum, Tokai will count as present shares that a stockholder holds even if the stockholder votes to abstain or only votes on one of the proposals. In addition, Tokai will count as present shares held in “street name” by brokers who indicate on their proxies that they do not have authority to vote those shares. If a quorum is not present, Tokai expects to adjourn the special meeting until it obtains a quorum.

Q: What vote is required to approve each matter and how are votes counted?

A: Proposal 1—Share Issuances Proposal

Approval of the Share Issuances Proposal requires the affirmative vote of a majority of the shares of Tokai common stock, present in person or represented by proxy and entitled to vote on the subject matter (excluding broker non-votes and abstentions).

Certain Tokai stockholders and directors and officers, who as of December 31, 2016 in the aggregate own approximately 36.3% of the outstanding shares of Tokai common stock, are parties to a Support Agreement with Tokai and Otic, under which such stockholders have agreed to vote in favor of the issuance of Tokai common stock in the Otic Transaction and against any “acquisition proposal.” For a more complete description of the Support Agreement, Tokai urges you to read the section entitled “*Agreements Related to the Share Purchase Agreement—Support Agreement*,” beginning on page 115 of this proxy statement.

Proposal 2—Reverse Stock Split Proposal

Approval of the Reverse Stock Split Proposal requires the affirmative vote of a majority of the shares of Tokai common stock outstanding and entitled to vote at the special meeting (broker non-votes and abstentions will have the same effect as voting against the Reverse Stock Split Proposal).

Proposal 3—Adjournment Proposal

Approval of the Adjournment Proposal requires the affirmative vote of a majority of the shares of Tokai common stock, present in person or represented by proxy and entitled to vote on the subject matter (excluding broker non-votes and abstentions).

Q: Who will count the vote?

A: The votes will be counted, tabulated and certified by Mediant Communications, Inc.

Q: Where can I find the voting results?

A: Tokai plans to announce preliminary voting results at the special meeting and will report final voting results in a Current Report on Form 8-K filed with the SEC within four business days following the date of the special meeting.

Q: Who will bear the costs of soliciting these proxies?

A: Tokai will bear the cost of soliciting proxies. In addition to solicitation by mail, Tokai’s directors, officers and employees may solicit proxies by telephone, e-mail, facsimile, and in person without additional compensation. Tokai may reimburse brokers or persons holding stock in their names, or in the names of their nominees, for their expenses in sending proxies and proxy material to beneficial owners.

Q: What is the Otic Transaction?

Tokai, Otic and the Sellers have entered into a Share Purchase Agreement, dated as of December 21, 2016. Under the Share Purchase Agreement, Tokai will acquire all of the ordinary and preferred shares of Otic in exchange for the issuance to the Sellers of a specified number of shares of Tokai common stock and will assume all outstanding share options and warrants of Otic. Accordingly, following the Otic Transaction, Otic will be a wholly owned subsidiary of Tokai.

Based on the outstanding share capital of Otic as of the date of the Share Purchase Agreement and the shares issuable upon exercise of warrants to purchase shares of Otic and the conversion of certain

[Table of Contents](#)

outstanding debt facilities of Otic into shares of Otic that are expected to be exercised or converted prior to the closing of the Otic Transaction, Tokai expects to issue _____ shares of Tokai common stock in the Otic Transaction. If all of Otic's outstanding options and warrants are exercised prior to closing, Tokai will issue a total of 36,911,631 shares of Tokai common stock in the Otic Transaction. Following the closing of the Otic Transaction, the stockholders of Otic are expected to hold approximately 60% of the outstanding shares of Tokai common stock, excluding for this purpose the effect on ownership of the issuance of shares in the Equity Financing. The relative percentage ownership of the combined company was derived using a stipulated value of Otic of approximately \$50.0 million and of Tokai of approximately \$33.0 million.

After the Otic Transaction, Tokai will change its corporate name to "OticPharma, Inc."

Q: Why are the two companies proposing the transaction?

A: The Otic Transaction will result in a pharmaceutical company focused on the development and commercialization of products for ENT disorders, including Otic's lead candidate, which is a nasally-administered, combination drug product (OP-02) intended to address the underlying cause of otitis media and Eustachian tube dysfunction ("*OM/ETD*"). For a discussion of Tokai's reasons for the Otic Transaction, Tokai urges you to read the section entitled "*The Otic Transaction—Reasons for the Otic Transaction*," beginning on page 81 of this proxy statement.

Q: What is the consideration to be paid by Tokai in the transaction?

A: At the closing of the transaction, all of the outstanding ordinary and preferred shares of Otic immediately prior to the closing of the Otic Transaction will be exchanged for a specified number of shares of Tokai common stock, and Tokai will assume all outstanding share options and warrants of Otic. Based on the number of outstanding shares of Otic as of the date of the Share Purchase Agreement, and shares issuable upon exercise of warrants to purchase shares of Otic and the conversion of certain outstanding debt facilities of Otic into shares of Otic that are expected to be exercised or converted prior to the closing of the Otic Transaction, Tokai expects to issue _____ shares of Tokai common stock in the Otic Transaction. If all of Otic's outstanding options and warrants are exercised prior to closing, Tokai will issue a total of 36,911,631 shares of Tokai common stock in the Otic Transaction. The consideration that each Seller will receive at closing depends on an allocation schedule that Otic will deliver to Tokai prior to closing, which reflects the consideration that each Seller is due upon closing of the Otic Transaction according to Otic's organizational documents. See "*Terms of the Share Purchase Agreement—Exchange Ratio*," beginning on page 98 of this proxy statement.

In connection with the Otic Transaction, each outstanding Otic option that is not exercised prior to the closing of the Otic Transaction will be assumed on the same terms and conditions as were applicable under the Otic share incentive plan, into an option to acquire such number of shares of Tokai common stock as is equal to the number of Otic shares subject to such unexercised option multiplied by _____, at a correspondingly adjusted exercise price.

In connection with the Otic Transaction, each outstanding warrant of Otic that is not exercised prior to the closing of the Otic Transaction will be assumed by Tokai on the same terms and conditions into a warrant to acquire such number of shares of Tokai common stock as is equal to the number of Otic shares subject to the warrant multiplied by _____, at a correspondingly adjusted exercise price.

Q: In addition to the requirement of obtaining Tokai stockholder approval, what else is required to consummate the Otic Transaction?

A: In addition to the requirement of obtaining Tokai stockholder approval, each of the other closing conditions set forth in the Share Purchase Agreement must be satisfied or waived, including:

- the filing, obtainment or occurrence of all authorizations and consents, including Israeli tax rulings described in the Share Purchase Agreement;

[Table of Contents](#)

- the absence of any order, executive order, stay, decree, judgment or injunction (preliminary or permanent) or statute, rule, or regulation prohibiting consummation of the Otic Transaction;
- the approval of an initial listing application on The NASDAQ Global Market with respect to the shares of Tokai common stock to be issued in the Otic Transaction;
- the accuracy of representations and warranties, subject to customary materiality standards;
- the performance of covenants in all material respects;
- the absence of any continuing Tokai or Otic material adverse effect; and
- resignations of the directors of Tokai who will not continue to serve as directors following closing of the Otic Transaction pursuant to the terms of the Share Purchase Agreement.

For a more complete description of the closing conditions under the Share Purchase Agreement, Tokai urges you to read the section entitled “*Terms of the Share Purchase Agreement—Conditions to the Consummation of the Otic Transaction*,” beginning on page 99 of this proxy statement.

Q: Who will be the directors of Tokai following the Otic Transaction?

A: The combined company’s board of directors will initially be fixed at seven members, consisting of (i) four members designated by Otic: Keith A. Katkin as Chairman, Gregory J. Flesher, Gary A. Lyons and Erez Chimovits and (ii) three board members designated by Tokai, which may include existing board members and up to one new member designated by Tokai. For more information on the leadership of the combined company following the transaction, see the section entitled “*Executive Officers and Directors Following the Otic Transaction*,” beginning on page 165 of this proxy statement.

Q: Who will be the executive officers of Tokai immediately following the Otic Transaction?

A: Immediately following the completion of the Otic Transaction, the executive management team of the combined company is expected to be composed of the current executive team of Otic: Gregory J. Flesher, serving as President and Chief Executive Officer, Christine G. Ocampo, serving as Chief Financial and Compliance Officer and Dr. Catherine C. Turkel, serving as Chief Development Officer. For more information on the leadership of the combined company following the transaction, see the section entitled “*Executive Officers and Directors Following the Otic Transaction*,” beginning on page 165 of this proxy statement.

Q: What will happen to Tokai if, for any reason, the Otic Transaction does not close?

A: If the Otic Transaction does not close for any reason, the Tokai board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of the various assets of Tokai, dissolve or liquidate the assets of Tokai or seek to continue to operate the business of Tokai. If Tokai seeks another strategic transaction or attempts to sell or otherwise dispose of the various assets of Tokai, there is no assurance that Tokai will be able to do so, that the terms would be equal to or superior to the terms of the Otic Transaction or as to the timing of such transaction. If Tokai decides to dissolve and liquidate its assets, Tokai would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying the debts and other obligations of Tokai and setting aside funds for reserves.

If Tokai were to seek to continue its business, it would need to complete its assessment of its galeterone and ARDA programs to determine whether and how to continue one or both of these development programs or acquire one or more other product candidates. Tokai would also need to raise funds to support continued operations and reassess its workforce requirements in consideration of its reduced workforce.

For information on reasons that the Otic Transaction might not close, see the sections entitled “*Terms of the Share Purchase Agreement—Conditions to the Consummation of the Otic Transaction*” and “*Terms*”

[Table of Contents](#)

of the *Share Purchase Agreement—Termination of the Share Purchase Agreement*,” beginning on pages 99 and 110, respectively. For more information on potential consequences for Tokai stockholders should the Otic Transaction not close, see the section entitled “*Risk Factors*,” beginning on page 29 of this proxy statement.

Q: When do you expect the Otic Transaction to be consummated?

A: Tokai anticipates that the closing of the Otic Transaction will occur sometime soon after the Tokai special meeting to be held on _____, 2017, but Tokai cannot predict the exact timing. For more information, please see the sections entitled “*Terms of the Share Purchase Agreement—Conditions to the Consummation of the Otic Transaction*,” beginning on page 99, and “*The Otic Transaction—Expected Timing of the Otic Transaction*,” beginning on page 71, each in this proxy statement.

Q: What are the material U.S. federal income tax consequences of the Otic Transaction to Tokai stockholders?

A: Tokai stockholders will not recognize gain or loss in connection with the Otic Transaction or the related Equity Financing with respect to their shares of Tokai common stock. For more information on the material U.S. federal income tax consequences of the Otic Transaction and the related Equity Financing to Tokai stockholders, see the section entitled “*The Otic Transaction—Material U.S. Federal Income Tax Consequences to Tokai Stockholders*,” beginning on page 95 of this proxy statement.

Q: What is the reverse stock split and why is it necessary?

A: Pursuant to the Share Purchase Agreement, Tokai agreed with Otic to seek stockholder approval for a reverse stock split with the specific terms to be proposed by Tokai and approved by Otic to the extent necessary in order to maintain Tokai’s listing on NASDAQ. Based on information currently available to Tokai, Tokai anticipates that it will be unable to meet the \$4.00 minimum bid price initial listing requirement at the closing of the Otic Transaction unless it effects a reverse stock split. Therefore Tokai is seeking to effect a reverse stock split of Tokai’s issued and outstanding shares of common stock, pursuant to which any number of outstanding shares between and including _____ and _____, such number to be determined by the Tokai board of directors at any time within _____ months of the date of the special meeting with the agreement of Otic, would be combined and reclassified into one share of Tokai common stock (the “*reverse stock split*”). The Tokai board of directors believes that the completion of the reverse stock split will cause the price of Tokai common stock to increase, which may encourage interest and trading in its common stock and may reduce the risk of a delisting of Tokai common stock from NASDAQ. There are no specified time restrictions on the reverse stock split. For more information on the reverse stock split, see the section entitled “*Reverse Stock Split Proposal*,” beginning on page 118 of this proxy statement.

Q: As a Tokai stockholder, how does the Tokai board of directors recommend that I vote?

A: The Tokai board of directors unanimously recommends that you vote (1) “FOR” the Share Issuances Proposal; (2) “FOR” the Reverse Stock Split Proposal; and (3) “FOR” the Adjournment Proposal. The approval by Tokai stockholders of the Share Issuances Proposal is required to complete the Otic Transaction described in this proxy statement. For more information on the Tokai board of directors’ recommendations to Tokai stockholders regarding the proposals to be voted on at the special stockholder meeting, see the section entitled “*The Otic Transaction—Recommendation of the Tokai Board of Directors*,” beginning on page 81 of this proxy statement.

Q: What risks should I consider in deciding whether to vote in favor of the proposals described in this proxy statement?

A: You should carefully review the section entitled “*Risk Factors*,” beginning on page 29 of this proxy statement, which sets forth certain risks and uncertainties related to the Otic Transaction, including risks and uncertainties to which Tokai, as an independent company, is subject, risks and uncertainties of the Otic business, which will be the business of the combined company following completion of the Otic Transaction, and additional risks and uncertainties to which the combined company will be subject.

**SELECTED HISTORICAL AND UNAUDITED PRO FORMA
COMBINED FINANCIAL INFORMATION**

Selected Historical Consolidated Financial Data of Tokai

The following table summarizes Tokai’s consolidated financial data. Tokai has derived the consolidated statement of operations data for the years ended December 31, 2015, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015 and 2014 from Tokai’s audited consolidated financial statements included elsewhere in this proxy statement. Tokai has derived the consolidated statement of operations data for the year ended December 31, 2012 and the consolidated balance sheet data as of December 31, 2013 and 2012 from Tokai’s audited consolidated financial statements not included in this proxy statement. The statement of operations data for the nine months ended September 30, 2016 and 2015 and the balance sheet data as of September 30, 2016 have been derived from Tokai’s unaudited financial statements included elsewhere in this proxy statement and have been prepared on the same basis as the audited financial statements. In the opinion of Tokai’s management, the unaudited financial data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. You should read the following selected consolidated financial data together with Tokai’s consolidated financial statements and the related notes appearing at the end of this proxy statement and the section entitled “Tokai’s Management’s Discussion and Analysis of Financial Condition and Results of Operations,” beginning on page 138 of this proxy statement. Tokai’s historical results are not necessarily indicative of results that should be expected in the future, and results for the nine months ended September 30, 2016 are not necessarily indicative of the results that should be expected for the full year ending December 31, 2016.

	Year Ended December 31,				Nine Months Ended September 30,	
	2015	2014	2013	2012	2016	2015
	(in thousands, except per share data)					
Statement of Operations Data:						
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Operating expenses:						
Research and development (1)	32,638	14,577	12,201	7,370	23,988	24,905
General and administrative (1)	12,623	8,885	3,548	2,279	10,375	9,284
Total operating expenses	45,261	23,462	15,749	9,649	34,363	34,189
Loss from operations	(45,261)	(23,462)	(15,749)	(9,649)	(34,363)	(34,189)
Interest and other income (expense), net	174	166	24	—	141	119
Net loss	(45,087)	(23,296)	(15,725)	(9,649)	(34,222)	(34,070)
Accretion of redeemable convertible preferred stock to redemption value	—	—	(94)	(34)	—	—
Net loss attributable to common stockholders	\$(45,087)	\$(23,296)	\$(15,819)	\$(9,683)	\$(34,222)	\$(34,070)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.01)	\$ (3.60)	\$ (38.02)	\$ (31.09)	\$ (1.51)	\$ (1.52)
Weighted average common shares outstanding, basic and diluted	22,484	6,469	416	311	22,632	22,449

[Table of Contents](#)

(1) Amounts include stock-based compensation expense as follows:

	Year Ended December 31,				Nine Months Ended September 30,	
	2015	2014	2013	2012	2016	2015
	(in thousands)					
Research and development	\$ 634	\$ 552	\$ 91	\$ 87	\$ 498	\$ 464
General and administrative	2,267	1,556	147	123	2,162	1,580
Total	<u>\$2,901</u>	<u>\$2,108</u>	<u>\$238</u>	<u>\$210</u>	<u>\$2,660</u>	<u>\$2,044</u>

	As of December 31,				As of
	2015	2014	2013	2012	September 30,
	(in thousands)				2016
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$63,957	\$105,256	\$ 31,753	\$ 11,691	\$ 34,718
Working capital	61,008	103,268	29,969	9,908	29,990
Total assets	67,974	107,744	32,287	11,962	36,721
Redeemable convertible preferred stock	—	—	85,345	49,845	—
Total stockholders' equity (deficit)	61,724	103,501	(55,267)	(39,901)	30,257

[Table of Contents](#)

Selected Historical Consolidated Financial Data of Otic

The following table summarizes Otic's consolidated financial data. Otic has derived the consolidated statements of operations data for the years ended December 31, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2015 and 2014 from Otic's audited consolidated financial statements included elsewhere in this proxy statement. The consolidated statement of operations data for the nine months ended September 30, 2016 and 2015 and the consolidated balance sheet data as of September 30, 2016 have been derived from Otic's unaudited consolidated financial statements included elsewhere in this proxy statement and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of Otic's management, the unaudited consolidated financial data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. You should read the following selected consolidated financial data together with Otic's consolidated financial statements and the related notes appearing at the end of this proxy statement and "Otic's Management's Discussion and Analysis of Financial Condition and Results of Operations," beginning on page 154 of this proxy statement. Otic's historical results are not necessarily indicative of results that should be expected in the future, and results for the nine months ended September 30, 2016 are not necessarily indicative of the results that should be expected for the full year ending December 31, 2016.

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2014	2016	2015
	(in thousands, except per share data)			
Statement of Operations Data:				
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	2,774	946	2,335	1,521
General and administrative	1,415	208	1,326	566
Total operating expenses	4,189	1,154	3,661	2,087
Loss from operations	(4,189)	(1,154)	(3,661)	(2,087)
Other income (expenses), net	(25)	(6)	(479)	17
Net loss	<u>\$ (4,214)</u>	<u>\$ (1,160)</u>	<u>\$ (4,140)</u>	<u>\$ (2,070)</u>
Net loss per share, basic and diluted	<u>\$ (1.13)</u>	<u>\$ (0.49)</u>	<u>\$ (1.01)</u>	<u>\$ (0.65)</u>
Weighted average ordinary shares outstanding, basic and diluted	<u>606</u>	<u>555</u>	<u>711</u>	<u>898</u>
	As of December 31,		As of September 30,	
	2015	2014	2016	
	(in thousands)			
Balance Sheet Data:				
Cash and cash equivalents	\$3,095	\$1,565	\$ 2,372	
Working capital (deficit)	2,693	1,477	(1,288)	
Total assets	3,298	1,637	2,529	
Total shareholders' equity (deficit)	2,782	1,503	(1,216)	

Selected Unaudited Pro Forma Combined Financial Data of Tokai and Otic

The following selected unaudited pro forma combined financial data presents the pro forma financial position and results of operations of the combined business based on the historical consolidated financial statements of Tokai and Otic, after giving effect to the Otic Transaction and the Equity Financing. The unaudited pro forma combined balance sheet data as of September 30, 2016 gives effect to the Otic Transaction and the Equity Financing as if each took place on September 30, 2016. The unaudited pro forma combined statement of operations data for the nine months ended September 30, 2016 and the year ended December 31, 2015 give effect to the Otic Transaction and the Equity Financing as if each took place on January 1, 2015. In the unaudited pro forma combined financial data, the Otic Transaction has been accounted for as a business combination, with Otic being the accounting acquirer. The allocation of purchase consideration reflected in the unaudited pro forma combined financial data is preliminary and will be adjusted based on the fair value of purchase consideration on the closing date of the Otic Transaction and upon completion of the final valuations of the fair value of the assets acquired and liabilities assumed of Tokai on the closing date of the Otic Transaction. Although Otic management believes that the fair values assigned to the assets to be acquired and liabilities to be assumed reflected in the unaudited pro forma combined financial data are based on reasonable estimates and assumptions using currently available data, the results of the final allocation could be materially different from the preliminary allocation.

The unaudited pro forma combined financial statements were prepared in accordance with Article 11 of SEC Regulation S-X. Accordingly, the historical consolidated financial data of Tokai and Otic has been adjusted to give pro forma effect to events that are (i) directly attributable to the Otic Transaction and the Equity Financing, (ii) factually supportable, and (iii) with respect to the unaudited pro forma combined statements of operations, expected to have a continuing impact on the combined results of operations of the combined company. In addition, the pro forma adjustments reflecting the completion of the Otic Transaction are based upon the application of the acquisition method of accounting in accordance with U.S. GAAP and upon the assumptions set forth in the unaudited pro forma combined financial statements.

The unaudited pro forma combined financial data is presented for illustrative purposes only and is not necessarily indicative of the financial condition or results of operations of future periods or the financial condition or results of operations that actually would have been realized had the entities been combined during the periods presented.

The following selected unaudited pro forma combined financial data should be read in conjunction with the section entitled “*Unaudited Pro Forma Combined Financial Information*,” beginning on page 171, Tokai’s audited and unaudited financial statements and the notes thereto included in this proxy statement beginning on page F-1, Otic’s audited and unaudited financial statements and the notes thereto beginning on page F-39, the sections entitled “*Tokai’s Management’s Discussion and Analysis of Financial Condition and Results of Operations*,” beginning on page 138, and “*Otic’s Management’s Discussion and Analysis of Financial Condition and Results of Operations*,” beginning on page 154, and the other information contained in this proxy statement.

[Table of Contents](#)

The following information does not give effect to the proposed reverse stock split of Tokai common stock described in the section entitled “Reverse Stock Split Proposal,” beginning on page 118 of this proxy statement.

	Pro Forma Combined	
	Year Ended December 31, 2015	Nine Months Ended September 30, 2016
	(in thousands, except per share data)	
Statement of Operations Data:		
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	35,412	26,323
General and administrative	14,038	11,651
Total operating expenses	49,450	37,974
Loss from operations	(49,450)	(37,974)
Other income (expense), net	149	179
Net loss	\$ (49,301)	\$ (37,795)
Net loss per share, basic and diluted	\$ (0.93)	\$ (0.67)
Weighted average common shares outstanding, basic and diluted	52,768	56,475
		Pro Forma Combined as of September 30, 2016 (in thousands)
Balance Sheet Data:		
Cash, cash equivalents and marketable securities		\$ 44,209
Working capital		33,242
Total assets		46,369
Total stockholders' equity		33,701

[Table of Contents](#)

Comparative Historical and Unaudited Pro Forma Per Share Data

The information below reflects historical per share information for Tokai and Otic and unaudited pro forma per share information of the combined company as if Tokai and Otic had been combined as of or for the periods presented. The per share amounts below do not give effect to the proposed reverse stock split of Tokai common stock described in the section entitled “Reverse Stock Split Proposal,” beginning on page 118 of this proxy statement.

The pro forma amounts in the tables below have been derived from the unaudited pro forma combined financial information included in the section entitled “Unaudited Pro Forma Combined Financial Information,” beginning on page 171 of this proxy statement. The pro forma amounts are presented for illustrative purposes only and are not necessarily indicative of what the financial position or the results of operations of the combined company would have been had Tokai and Otic been combined as of or for the periods presented.

The tables below should be read in conjunction with the audited and unaudited consolidated financial statements of Tokai and the related notes, the audited and unaudited consolidated financial statements of Otic and the related notes, and the unaudited pro forma combined financial information and the related notes, all of which are included elsewhere in this proxy statement.

TOKAI

	As of or for the Year Ended December 31, 2015	As of or for the Nine Months Ended September 30, 2016
Historical Per Common Share Data:		
Basic and diluted net loss per share	\$ (2.01)	\$ (1.51)
Book value per share	\$ 2.73	\$ 1.34
Cash dividends declared per share	\$ —	\$ —

OTIC

	As of or for the Year Ended December 31, 2015	As of or for the Nine Months Ended September 30, 2016
Historical Per Ordinary Share Data:		
Basic and diluted net loss per share	\$ (1.13)	\$ (1.01)
Book value per share	\$ 3.97	\$ (1.64)
Cash dividends declared per share	\$ —	\$ —
Pro Forma Equivalent Common Share Data:		
Basic and diluted net loss per share	\$ (0.27)	\$ (0.24)
Book value per share	\$ 0.93	\$ (0.39)
Cash dividends declared per share	\$ —	\$ —

UNAUDITED PRO FORMA COMBINED

	As of or for the Year Ended December 31, 2015	As of or for the Nine Months Ended September 30, 2016
Pro Forma Per Common Share Data:		
Basic and diluted net loss per share	\$ (0.93)	\$ (0.67)
Book value per share	N/A	\$ 0.58
Cash dividends declared per share	\$ —	\$ —

DESCRIPTION OF TOKAI COMMON STOCK

The following description of Tokai's capital stock is intended as a summary only and therefore is not a complete description of Tokai's capital stock. This description is based upon, and is qualified by reference to, Tokai's certificate of incorporation, Tokai's by-laws and applicable provisions of Delaware corporate law. You should read Tokai's certificate of incorporation and by-laws for the provisions that are important to you.

Tokai's authorized capital stock consists of 200,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of December 31, 2016, 22,641,651 shares of common stock were outstanding and no shares of preferred stock were outstanding.

Common Stock

Annual Meeting

Annual meetings of Tokai's stockholders are held on the date designated in accordance with Tokai's by-laws. Written notice must be mailed to each stockholder entitled to vote not less than ten nor more than 60 days before the date of the meeting. The presence in person or by proxy of the holders of record of a majority of Tokai's issued and outstanding shares entitled to vote at such meeting constitutes a quorum for the transaction of business at meetings of the stockholders. Special meetings of the stockholders may be called for any purpose only by the board of directors, and business transacted at any special meetings of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of such meeting. Except as may be otherwise provided by applicable law, Tokai's certificate of incorporation or Tokai's by-laws, all elections shall be decided by a plurality, and all other questions shall be decided by a majority, of the votes cast by stockholders entitled to vote thereon at a duly held meeting of stockholders at which a quorum is present.

Voting Rights

Each holder of common stock is entitled to one vote for each share held on all matters to be voted upon by stockholders.

Dividends

The holders of common stock, after any preferences of holders of any preferred stock, are entitled to receive dividends when and if declared by the board of directors out of legally available funds.

Liquidation and Dissolution

If Tokai is liquidated or dissolved, the holders of the common stock will be entitled to share in Tokai's assets available for distribution to stockholders in proportion to the amount of common stock they own. The amount available for common stockholders is calculated after payment of liabilities. Holders of any preferred stock will receive a preferential share of Tokai's assets before the holders of the common stock receive any assets.

Other Rights

Holders of common stock have no right to:

- convert the stock into any other security;
- have the stock redeemed;
- purchase additional stock; or
- maintain their proportionate ownership interest.

[Table of Contents](#)

The common stock does not have cumulative voting rights. Holders of shares of the common stock are not required to make additional capital contributions.

Transfer Agent and Registrar

Continental Stock Transfer & Trust Company is transfer agent and registrar for the common stock.

Preferred Stock

Under the terms of Tokai's certificate of incorporation, Tokai's board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Tokai's board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing Tokai's board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of Tokai's outstanding voting stock. There are no shares of preferred stock outstanding, and Tokai has no present plans to issue any shares of preferred stock.

Stock Options

As of December 31, 2016, there were options to purchase a total of 1,896,169 shares of Tokai common stock outstanding at a weighted average exercise price of \$6.55 per share.

Provisions of Tokai's Certificate of Incorporation and By-laws and Delaware Law That May Have Anti-Takeover Effects

Staggered Board; Removal of Directors

Tokai's certificate of incorporation and by-laws divide its board of directors into three classes with staggered three-year terms. In addition, a director is only able to be removed for cause and only by the affirmative vote of the holders of at least 75% of the votes that all of Tokai stockholders would be entitled to cast in an annual election of directors. Any vacancy on the Tokai board of directors, including a vacancy resulting from an enlargement of the board of directors, may only be filled by vote of a majority of the directors then in office. The classification of the board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of Tokai.

Stockholder Action by Written Consent; Special Meetings

Tokai's certificate of incorporation provides that any action required or permitted to be taken by its stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Tokai's certificate of incorporation and by-laws also provide that, except as otherwise required by law, special meetings of Tokai's stockholders can only be called by the board of directors.

Advance Notice Requirements for Stockholder Proposals

Tokai's by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder of record on the

[Table of Contents](#)

record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to Tokai's secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of Tokai's outstanding voting securities.

Delaware Business Combination Statute

Tokai is subject to Section 203 of the Delaware General Corporate Law ("**DGCL**"). Subject to certain exceptions, Section 203 prevents a publicly-held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of the board of directors or unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving Tokai and the "interested stockholder" and the sale of more than 10% of Tokai's assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of Tokai's outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon closing of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. Tokai has not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of Tokai may be discouraged or prevented. However, on December 21, 2016, the Tokai board of directors approved the transaction contemplated by the Share Purchase Agreement, rendering Section 203 inapplicable to the Otic Transaction to the fullest extent permitted by applicable law.

Amendment of Certificate of Incorporation and By-laws

The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Tokai's by-laws may be amended or repealed by a majority vote of its board of directors or by the affirmative vote of the holders of at least 75% of the votes that all of Tokai's stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all of Tokai's stockholders would be entitled to cast in any annual election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of Tokai's certificate of incorporation described above under "*—Staggered Board; Removal of Directors*" and "*—Stockholder Action by Written Consent; Special Meetings.*"

[Table of Contents](#)

NASDAQ Global Market Listing

Tokai common stock is quoted on The NASDAQ Global Market under the symbol “TKAI.” The Share Purchase Agreement requires Tokai to use its commercially reasonable efforts to continue its existing listing on NASDAQ, to obtain approval of the listing of the combined company on NASDAQ and to cause the shares of Tokai common stock being issued in the Otic Transaction to be approved for listing, subject to notice of issuance, on NASDAQ at or prior to the consummation of the Otic Transaction. Tokai, in coordination with Otic, intends to file certain notifications, including an initial listing application with NASDAQ, in satisfaction of Tokai’s obligations under the Share Purchase Agreement, and toward fulfillment of a condition to the consummation of the Otic Transaction under the Share Purchase Agreement (which is more fully described in the section of this proxy statement entitled, “*Terms of the Share Purchase Agreement—Conditions to the Consummation of the Otic Transaction*”).

MARKET PRICE AND DIVIDEND INFORMATION

Market Price of Tokai Common Stock

Tokai's common stock trades under the symbol "TKAI" on The NASDAQ Global Market and has been publicly traded since September 17, 2014. Prior to this time, there was no public market for Tokai's common stock. The following table sets forth the high and low sales price of Tokai's common stock as reported on The NASDAQ Global Market for the periods indicated. These per share prices do not give effect to the proposed reverse stock split of Tokai common stock, which is intended to be implemented prior to the consummation of the Otic Transaction.

	<u>High</u>	<u>Low</u>
Year Ended December 31, 2015		
First quarter	\$16.10	\$11.10
Second quarter	\$14.45	\$ 9.77
Third quarter	\$14.71	\$ 9.95
Fourth quarter	\$12.93	\$ 8.50
Year Ended December 31, 2016		
First quarter	\$ 8.63	\$ 4.93
Second quarter	\$ 8.80	\$ 5.03
Third quarter	\$ 5.86	\$ 0.98
Fourth quarter	\$ 2.09	\$ 0.73
Year Ending December 31, 2017		
First quarter (through January 20, 2017)	\$ 1.12	\$ 0.96

On December 21, 2016, the last trading day prior to the Tokai board of directors' approval of the Otic Transaction, the reported closing price for Tokai common stock was \$1.01 per share. On _____, 2017, the latest practicable trading date before the filing of this proxy statement, the reported closing price of Tokai common stock was \$ _____ per share.

Because the price of Tokai common stock is subject to fluctuation, the market value of the shares of Tokai common stock that Otic shareholders will be entitled to receive pursuant to the terms of the Share Purchase Agreement may increase or decrease.

Assuming approval of the application for initial listing with the NASDAQ Stock Market LLC, following the consummation of the Otic Transaction, Tokai common stock will be listed on The NASDAQ Global Market and will trade under Tokai's new name, "OticPharma, Inc." and new trading symbol, "AOME."

As of _____, 2017, the record date for the Tokai special meeting, Tokai had approximately _____ holders of its common stock. For detailed information regarding the beneficial ownership of certain stockholders of Tokai, see the section entitled "*Security Ownership of Certain Beneficial Owners and Management of Tokai*," beginning on page 169 of this proxy statement.

Dividends

Neither Tokai nor Otic has ever declared or paid cash dividends on its capital stock. Any determination to pay dividends following consummation of the Otic Transaction or otherwise will be at the discretion of Tokai's then-current board of directors and will depend upon a number of factors, including its results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors Tokai's then-current board of directors deems relevant.

RISK FACTORS

In addition to the other information contained in this proxy statement, including the matters addressed in the section entitled “Cautionary Statement Regarding Forward-Looking Information,” beginning on page 64 of this proxy statement, you should carefully consider the following risk factors when deciding whether to vote to approve the proposals described in this proxy statement. You should also consider the information in our other reports on file with the SEC that are incorporated by reference into this proxy statement, including the risks related to the Tokai business that are incorporated by reference from Tokai’s Quarterly Report on Form 10-Q filed on November 3, 2016. See “Where You Can Find More Information; Incorporation by Reference,” beginning on page 182 of this proxy statement.

The following sets forth certain risks and uncertainties related to the Otic Transaction, including risks and uncertainties to which Tokai, as an independent company, is subject, risks and uncertainties related to the Otic business, which will be the business of the combined company following completion of the Otic Transaction, and additional risks and uncertainties to which the combined company will be subject.

Risks Related to the Otic Transaction

Because the exchange ratio is fixed and the market price of Tokai common stock has fluctuated and may continue to fluctuate, the Otic Transaction consideration at the closing may have a greater or lesser value than at the time the Share Purchase Agreement was signed.

The Share Purchase Agreement has fixed the exchange ratio for the Otic ordinary and preferred shares, as described more fully in the section entitled “Terms of the Share Purchase Agreement—Exchange Ratio,” beginning on page 98 of this proxy statement. Any changes in the market price of Tokai common stock before the completion of the Otic Transaction will not affect the number of shares Otic securityholders will be entitled to receive pursuant to the Share Purchase Agreement. Therefore, if before the completion of the Otic Transaction the market price of Tokai common stock increases from the market price on the date of the Share Purchase Agreement, then Otic securityholders could receive Otic Transaction consideration with substantially more value for their shares of Otic capital stock than the parties had negotiated for in the establishment of the exchange ratio. Stock price changes may result from a variety of factors, including, among others, general market and economic conditions, changes in Tokai’s businesses, operations and prospects, market assessments of the likelihood that the Otic Transaction will be completed, the timing of the Otic Transaction, regulatory considerations and other risk factors set forth or incorporated by reference in this proxy statement. Many of these factors are beyond Tokai’s control.

Because the lack of a public market for Otic shares makes it difficult to evaluate the fairness of the transaction, Tokai may pay more than the fair market value of the Otic shares.

The outstanding capital stock of Otic is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Otic. Because the percentage of Tokai equity to be issued to Otic shareholders was determined based on negotiations between the parties, it is possible that the value of the Tokai common stock to be received by Otic shareholders will be less than the fair market value of Otic, or that the value of the Tokai common stock to be received by Otic shareholders will be more than the fair market value of Otic.

The Otic Transaction may be consummated even though material adverse changes may result solely from the announcement of the transaction, changes in the industry in which Tokai and Otic operate that apply to all companies generally and other causes.

In general, either Tokai or Otic can refuse to complete the Otic Transaction if there is a material adverse effect affecting the other party between December 21, 2016, the date of the Share Purchase Agreement, and the

[Table of Contents](#)

closing. However, certain types of changes do not permit either party to refuse to complete the transaction, even if such change could be deemed to have a material adverse effect on Tokai or Otic, including:

- any changes in prevailing economic or market conditions in the United States or any other jurisdiction in which Tokai or Otic has substantial business operations, except to the extent those changes have a disproportionate effect on Tokai or Otic and their respective subsidiaries relative to the other participants in the industry or industries in which Tokai or Otic and their respective subsidiaries operate in the relevant jurisdiction;
- changes or events affecting the industry or industries in which Tokai or Otic and their respective subsidiaries operate generally, except to the extent those changes or events have a disproportionate effect on Tokai or Otic and their respective subsidiaries relative to the other participants in the industry or industries in which Tokai or Otic and their respective subsidiaries;
- changes in generally accepted accounting principles or requirements applicable to Tokai or Otic and their respective subsidiaries, except to the extent those changes or events have a disproportionate effect on Tokai or Otic and their respective subsidiaries relative to the other participants in the industry or industries in which Tokai or Otic and their respective subsidiaries operate;
- changes in laws, rules or regulations of general applicability or interpretations thereof by any governmental entity, except to the extent those changes or events have a disproportionate effect on Tokai or Otic and their respective subsidiaries relative to the other participants in the industry or industries in which Tokai or Otic and their respective subsidiaries operate;
- any natural disaster or any outbreak of major hostilities in which the United States, or in the case of Otic, Israel, is involved or any act of terrorism within the United States or in the case of Otic, Israel, or directed against their facilities or citizens wherever located, except to the extent those changes or events have a disproportionate effect on Tokai or Otic and their respective subsidiaries relative to the other participants in the industry or industries in which Tokai or Otic and their respective subsidiaries operate;
- any failure by Tokai or Otic to meet any internal guidance, budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations;
- with respect to Tokai, a change in the public trading price or trading volume of Tokai's common stock or the implications thereof; and
- with respect to Tokai, any failure by Tokai to meet any public estimates or expectations of Tokai's revenue, earnings or other financial performance or results of operations for any period.

If material adverse effects occur and Tokai and Otic still complete the transaction, the combined company's stock price may suffer.

Tokai's officers and directors have interests in the Otic Transaction that may be different from, or in addition to, your interests as a stockholder of Tokai may generally.

When considering the recommendation of the Tokai board of directors that Tokai stockholders approve the proposals described in this proxy statement, Tokai stockholders should be aware that officers and directors of Tokai have certain interests in the Otic Transaction that may be different from, or in addition to, the interests of Tokai stockholders more generally. These interests generally include, among others, the special treatment of outstanding stock options, the right to certain enhanced change in control severance compensation and benefits and continued indemnification, expense advancement and insurance coverage. For more information concerning the interests of Tokai executive officers and directors, see the section entitled "*The Otic Transaction—Interests of Tokai's Directors and Executive Officers*," beginning on page 83 of this proxy statement.

As a result of these interests, these officers and directors of Tokai might be more likely to support and to vote in favor of the proposals described in this proxy statement than if they did not have these interests.

[Table of Contents](#)

Tokai stockholders may not realize a benefit from the Otic Transaction commensurate with the ownership dilution they will experience in connection with the Otic Transaction.

Tokai stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the consummation of the Otic Transaction. Under the Share Purchase Agreement, upon the closing, Tokai stockholders are expected to hold approximately 40% of the outstanding common stock of the combined company. If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the transaction, Tokai stockholders will have experienced substantial dilution of their ownership, voting and other interests in Tokai without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the transaction.

During the pendency of the Otic Transaction, Tokai may not be able to enter into a business combination with another party under certain circumstances because of restrictions in the Share Purchase Agreement, which could adversely affect its business.

Covenants in the Share Purchase Agreement impede the ability of Tokai to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Otic Transaction. As a result, if the Otic Transaction is not completed, Tokai may be at a disadvantage to its competitors during that period. For more information on covenants that restrict Tokai's ability to enter into such transactions during the pendency of the Share Purchase Agreement, see the section entitled "Terms of the Share Purchase Agreement—Covenants; Conduct of the Businesses," beginning on page 104 of this proxy statement.

Certain provisions of the Share Purchase Agreement may discourage third parties from submitting alternative acquisition proposals, including proposals that may be superior to the arrangements contemplated by the Share Purchase Agreement.

The terms of the Share Purchase Agreement prohibit each of Tokai and Otic from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and is reasonably capable of being consummated. In addition, if Tokai or Otic terminates the Share Purchase Agreement under certain circumstances, including terminating because of a decision of the Tokai board of directors to recommend a superior proposal, Tokai would be required to pay a termination fee of \$1.0 million to Otic. This termination fee may discourage third parties from submitting alternative takeover proposals to Tokai or Otic or their stockholders, and may cause the respective boards of directors to be less inclined to recommend an alternative proposal.

The combined company's common stock could be delisted from NASDAQ if Tokai and Otic fail to comply with NASDAQ's listing standards.

Pursuant to NASDAQ's Listing Rules, consummation of the Otic Transaction requires the combined company to submit an initial listing application and, at the time of the transaction, meet all of the criteria applicable to a company initially requesting listing. While Tokai and Otic intend to obtain listing status for the combined company and maintain the same, no guarantees can be made about Tokai's and Otic's ability to do so. Approval of an initial listing application is a closing condition of the Share Purchase Agreement, and failure to have such listing approved may prevent the Otic Transaction from closing.

If the combined company's common stock is delisted by NASDAQ, the common stock may be eligible to trade on the OTC Bulletin Board or another over-the-counter market. Any such alternative would likely result in it being more difficult for the company to raise additional capital through the public or private sale of equity securities and for investors to dispose of, or obtain accurate quotations as to the market value of, the common stock. In addition, there can be no assurance that the common stock would be eligible for trading on any such alternative exchange or markets.

[Table of Contents](#)

The announcement and pendency of the Otic Transaction, whether or not consummated, may adversely affect the trading price of Tokai's common stock and its business prospects.

The announcement and pendency of the Otic Transaction, whether or not consummated, may adversely affect the trading price of Tokai's common stock and its business prospects. In the event that the Otic Transaction is not completed, the announcement of the termination of the Share Purchase Agreement may also adversely affect the trading price of Tokai's common stock and its business prospects.

Tokai and Otic may become involved in securities class action litigation or shareholder derivative litigation in connection with the Otic Transaction that could divert management's attention and harm the combined company's business and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action or stockholder derivative litigation has often followed the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. The combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect the combined company's business.

Failure to consummate the Otic Transaction may result in Tokai paying a termination fee to Otic and could harm the common stock price of Tokai and future business and operations of Tokai.

The Otic Transaction will not be consummated if the conditions precedent to the consummation of the transaction, as discussed more fully in the section entitled "*Terms of the Share Purchase Agreement—Conditions to the Consummation of the Otic Transaction*," beginning on page 99 of this proxy, are not satisfied or waived, or if the Share Purchase Agreement is terminated in accordance with its terms, as described more fully in the section entitled "*Terms of the Share Purchase Agreement—Termination of the Share Purchase Agreement*," beginning on page 110 of this proxy statement. If the Otic Transaction is not consummated, Tokai is subject to the following risks:

- if the Share Purchase Agreement is terminated under certain circumstances, Tokai will be required to pay Otic a termination fee of \$1.0 million; and
- the price of Tokai common stock may decline and remain volatile.

If the Otic Transaction does not close for any reason, the Tokai board of directors may elect to, among other things, attempt to complete another strategic transaction, attempt to sell or otherwise dispose of the various assets of Tokai, dissolve or liquidate the assets of Tokai or seek to continue to operate the business of Tokai. If Tokai seeks another strategic transaction or attempts to sell or otherwise dispose of the various assets of Tokai, there is no assurance that Tokai will be able to do so, that the terms would be equal to or superior to the terms of the Otic Transaction or as to the timing of such transaction. If Tokai decides to dissolve and liquidate its assets, Tokai would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to stockholders after paying the debts and other obligations of Tokai and setting aside funds for reserves.

If Tokai were to seek to continue its business, it would need to complete its assessment of its galeterone and ARDA programs to determine whether and how to continue one or both of these development programs or acquire one or more other product candidates. Tokai would also need to raise funds to support continued operations and re-assess its workforce requirements in consideration of its reduced workforce.

If Tokai does not successfully consummate the Otic Transaction, the Tokai board of directors may attempt to continue its business. Tokai will need substantial additional funding to continue its development of, and to commercialize, galeterone or any future product candidate, which funding may not be available on acceptable

[Table of Contents](#)

terms, or at all. If Tokai is unable to raise capital when needed, it may be forced to delay, reduce, terminate or eliminate product development programs.

As of September 30, 2016, Tokai had cash, cash equivalents and marketable securities of \$34.7 million. Tokai has devoted a significant portion of its cash resources to the development of galeterone and its ARMOR3-SV trial. However, in July 2016, Tokai announced its plan to discontinue the ARMOR3-SV clinical trial. While Tokai has entered into the Share Purchase Agreement, Tokai's operating plan may change or the consummation of the Otic Transaction may be delayed or may not occur at all. If the Otic Transaction with Otic is not consummated and Tokai decides to continue its historical business operations, Tokai may require substantial additional funding to operate.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and Tokai may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, galeterone and any future product candidates, if approved, may not achieve commercial success. Tokai's commercial revenues, if any, will be derived from sales of products that Tokai does not expect to be commercially available for several years, if at all. Accordingly, Tokai will need to continue to rely on additional financing to achieve its business objectives. Additional financing may not be available to Tokai on acceptable terms, or at all. If adequate funds are not available to Tokai on a timely basis, Tokai may be required to curtail its operations.

If Tokai does not successfully consummate the transaction with Otic, the Tokai board of directors may dissolve or liquidate the assets to pursue a dissolution and liquidation of Tokai. In such an event, the amount of cash available for distribution to Tokai's stockholders will depend heavily on the timing of such transaction or liquidation.

If the Otic Transaction does not close for any reason, the Tokai board of directors may elect to, among other things, dissolve or liquidate the assets of Tokai. If Tokai decides to dissolve and liquidate its assets, Tokai would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to stockholders after paying the debts and other obligations of Tokai and setting aside funds for reserves.

In the event of a dissolution and liquidation, the amount of cash available for distribution to Tokai's stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as Tokai funds its operations in preparation for the consummation of the Otic Transaction. Further, the Share Purchase Agreement contains certain termination rights for each party, and provides that, upon termination under specified circumstances, Tokai may be required to pay Otic a termination fee of \$1.0 million, which would further decrease Tokai's available cash resources. If the Tokai board of directors were to approve and recommend, and Tokai's stockholders were to approve, a dissolution and liquidation of Tokai, Tokai would be required under Delaware corporate law to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to Tokai stockholders. Tokai's commitments and contingent liabilities may include (i) regulatory and clinical obligations remaining under Tokai's clinical trials; (ii) obligations under Tokai's employment and separation agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of Tokai; and (iii) potential litigation against Tokai, and other various claims and legal actions arising in the ordinary course of business. As a result of this requirement, a portion of Tokai's assets may need to be reserved pending the resolution of such obligations. In addition, Tokai may be subject to litigation or other claims related to a dissolution and liquidation of Tokai. If a dissolution and liquidation were pursued, the Tokai board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of Tokai common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of Tokai.

[Table of Contents](#)

Risks Related to the Otic Business

Risks Related to Otic's Financial Position and Need for Additional Capital

Otic has incurred significant losses since its inception.

Since inception, Otic has incurred significant operating losses. Otic's net loss was \$4.2 million for the year ended December 31, 2015 and \$4.1 million for the nine months ended September 30, 2016. As of September 30, 2016, Otic had an accumulated deficit of \$12.9 million. Otic has focused primarily on its discovery efforts and developing its product candidates. Otic is continuing or preparing for clinical development of its lead product candidates, OP-01, for the treatment of Acute Otitis Externa ("*AOE*"), and OP-02, for the treatment of Otitis Media ("*OM*") and Eustachian Tube Dysfunction ("*ETD*"), and expects that it will be several years, if ever, before Otic has a product candidate ready for commercialization. To date, Otic has financed its operations primarily through private placements of its preferred stock.

Otic's short operating history may make it difficult to evaluate the success of its business to date and to assess its future viability.

Otic is an early stage clinical development company. Otic commenced active operations in 2008. Its operations to date have been limited to organizing and staffing the company, business planning, raising capital, acquiring and developing technology, identifying potential product candidates, undertaking preclinical studies and early stage clinical studies of its most advanced product candidate, OP-01, which Otic is undertaking additional reformulation work for and preparing to repeat early-stage clinical development and studies. Additional operations related to Otic's other technology, OP-02, includes arranging for a third party to manufacture material using current Good Manufacturing Procedures ("*cGMP*") and preparing for a phase 1 clinical studies. Otic has not yet demonstrated its ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful product commercialization. It can take many years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about Otic's future success or viability based on its short operating history to date may not be as accurate as they could be if Otic had a longer operating history.

In addition, as an early stage business, Otic may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To successfully market any of its product candidates, Otic will need to transition from a company with a clinical development focus to a company capable of supporting commercial activities. Otic may not be successful in such a transition.

Risks Related to the Development of Otic's Product Candidates

Otic is early in its development efforts and has only two drug candidates, OP-01 and OP-02, in preclinical or clinical development. If Otic is unable to successfully develop and commercialize OP-01 or OP-02 or if it experiences significant delays in doing so, the business will be materially harmed.

Otic currently does not have any products that have gained regulatory approval. Otic has invested substantially all of its efforts and financial resources in product development and funding its preclinical and clinical studies. Otic's ability to generate product revenues, which it does not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of OP-01, OP-02 and additional product candidates. As a result, the business is substantially dependent on Otic's ability to complete the development of and obtain regulatory approval for OP-01 and OP-02.

Otic has not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. For example, to execute its business plan, Otic will need to successfully:

- execute OP-01 and OP-02 development activities;

Table of Contents

- in-license or acquire other product candidates and advance them through clinical development;
- obtain required regulatory approvals for the development and commercialization of OP-01, OP-02 or other product candidates;
- maintain, leverage and expand its intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on its own or in collaboration with strategic partners;
- gain market acceptance for OP-01, OP-02 and other product candidates;
- obtain and maintain adequate product pricing and reimbursement;
- develop and maintain any strategic relationships Otic elects to enter into; and
- manage its spending as costs and expenses increase due to product manufacturing, preclinical development, clinical trials, regulatory approvals and commercialization.

If Otic is unsuccessful in accomplishing these objectives, Otic may not be able to successfully develop and commercialize OP-01, OP-02 or other product candidates, and its business will suffer.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome including failure to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States. Otic may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of its product candidates.

Otic has recently commenced reformulation work for OP-01 in order to explore adding a second active ingredient to address the pain associated with infections. Repeated early-stage clinical work for OP-01 is expected once the reformulation work is concluded and there is a risk that subsequent studies will not match results seen in prior studies. OP-02 is preparing to enter phase 1 clinical development. Given the early stage of clinical development, the risk of failure for all of Otic's product candidates is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, Otic must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidates in humans. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Further, the results of preclinical studies and early clinical trials of its product candidates as well as earlier generation formulations may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. For instance, the results of Otic's studies with earlier generation formulations of OP-01 may not be predictive of the results of studies conducted with a different formulation of OP-01. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. It is impossible to predict when or if any of Otic's product candidates will prove effective or safe in humans or will receive regulatory approval.

Otic may experience delays in its clinical trials, and it does not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the European Medicines Agency (the "EMA"), Medicines & Healthcare Products Regulatory Agency (the "MHRA"), the UK regulatory authority, or U.S. Food and Drug Administration (the "FDA") will not put any of its product candidates on clinical hold in the future. Otic may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive marketing approval or commercialize its product candidates. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the EMA, MHRA, FDA or a comparable foreign regulatory authority on a trial design that Otic wants to execute;

Table of Contents

- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial, including the possibility Otic could learn of additional subjects who were exposed by predecessor IND sponsors to investigational drugs outside of clinical protocols;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of its contract research organizations (“*CROs*”) and other third parties;
- clinical trials of its product candidates may produce negative or inconclusive results, and Otic may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of its product candidates may be larger than Otic anticipates, enrollment in these clinical trials may be slower than it anticipates or participants may drop out of these clinical trials at a higher rate than it anticipates;
- Otic may experience delays or difficulties in the enrollment of patients that its product candidates are designed to target;
- its third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to it in a timely manner, or at all;
- Otic may have difficulty partnering with experienced CROs and study sites that can identify patients that its product candidates are designed to target and run its clinical trials effectively;
- regulators or institutional review boards (“*IRBs*”) may require that Otic or its investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of its product candidates may be greater than Otic anticipates;
- the supply or quality of its product candidates or other materials necessary to conduct clinical trials of its product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions.

If Otic is required to conduct additional clinical trials or other testing of its product candidates beyond those that it currently contemplates, if Otic is unable to successfully complete clinical trials of its product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, Otic may:

- be delayed in obtaining marketing approval for its product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

[Table of Contents](#)

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for its products or inhibit its ability to successfully commercialize its products;
- be subject to additional post-marketing restrictions and/or testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Otic's product development costs will also increase if it experiences delays in testing or marketing approvals. Otic does not know whether any of its preclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which Otic may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before it does and impair its ability to successfully commercialize its product candidates and may harm its business and results of operations.

If Otic experiences delays or difficulties in the enrollment of patients in clinical trials, its receipt of necessary regulatory approvals could be delayed or prevented and expenses for development of its product candidates could increase.

Otic may not be able to initiate or continue clinical trials for its product candidates if Otic is unable to locate and enroll a sufficient number of eligible patients to participate in these trials to demonstrate safety and efficacy. Otic has yet to initiate the first clinical studies of OP-02 and plans to reformulate and initiate the clinical studies of OP-01 in the future, and it does not know whether the planned or ongoing clinical trials will enroll subjects in a timely fashion, require redesign of essential trial elements or be completed on its projected schedule. In addition, competitors may have ongoing clinical trials for product candidates that treat related or same indications as its product candidates, and patients who would otherwise be eligible for its clinical trials may instead enroll in clinical trials of its competitors' product candidates. Otic's inability to enroll a sufficient number of patients for its clinical trials would result in significant delays and could require it to abandon one or more clinical trials altogether.

Patient enrollment is affected by other factors including:

- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same disease indication;
- the patient referral practices of physicians;
- the proximity and availability of clinical trial sites for prospective patients;
- ambiguous or negative interim results of its clinical trials, or results that are inconsistent with earlier results;
- feedback from the EMA, MHRA, FDA, IRBs, data safety monitoring boards, or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical and clinical studies, that might require modifications to the protocol;
- decisions by the EMA, MHRA, FDA, IRBs, a comparable foreign regulatory authority or Otic, or recommendations by data safety monitoring boards, to suspend or terminate clinical trials at any time for safety issues or for any other reason; and
- unacceptable risk-benefit profile or unforeseen safety issues or adverse effects.

[Table of Contents](#)

Enrollment delays in Otic's clinical trials may result in increased development costs for its product candidates, which would cause the value of its company to decline and limit its ability to obtain additional financing.

If serious adverse events or unacceptable side effects are identified during the development of its product candidates, Otic may need to abandon or limit its development of some of its product candidates.

If Otic's product candidates are associated with undesirable effects in preclinical or clinical trials or have characteristics that are unexpected, Otic may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. OP-01 and OP-02 are early clinical phase product candidates, and the side effect profile in humans has not been fully established. Although the one reported serious adverse event in Otic's Phase 2 study of OP-01 was determined not to be drug related, other adverse events may arise and the occurrence of adverse events, whatever the cause, may impact the conduct of future clinical studies. Though currently unknown, drug-related side effects may be identified through further clinical studies and, as such these possible drug-related side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may harm Otic's business, financial condition and prospects significantly.

Risks Related to Regulatory Approval of Otic's Product Candidates and Other Legal Compliance Matters

If Otic is not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may be for a more narrow indication than expected, Otic will not be able to commercialize its product candidates, and its ability to generate revenue will be materially impaired.

Otic's product candidates must be approved by the FDA pursuant to a new drug application ("*NDA*") in the United States and by the EMA or similar regulatory authorities outside the United States prior to commercialization. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes several years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent Otic from commercializing the product candidate. Otic has not received approval to market any of its product candidates from regulatory authorities in any jurisdiction. Otic has no experience in filing and supporting the applications necessary to gain marketing approvals and may engage third-party consultants to assist in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Otic's product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that its data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

Any marketing approval Otic ultimately obtains may be for fewer or more limited indications than requested or subject to restrictions or post-approval commitments that render the approved product not commercially viable or its market potential significantly impaired. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of Otic's product candidates.

[Table of Contents](#)

If Otic experiences delays in obtaining approval or if it fails to obtain approval of its product candidates, the commercial prospects for its product candidates may be harmed and its ability to generate revenues will be materially impaired.

Failure to obtain marketing approval in international jurisdictions would prevent Otic's product candidates from being marketed abroad.

In order to market and sell its products in the European Union and many other jurisdictions, Otic or its third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain EMA, MHRA or FDA approval. The regulatory approval process outside the European Union, United Kingdom and United States generally includes all of the risks associated with obtaining, respectively, EMA, MHRA or FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Otic or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the EMA, MHRA or FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Otic may not be able to file for marketing approvals and may not receive necessary approvals to commercialize its products in any market.

Any product candidate for which Otic obtains marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and Otic may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with its products, when and if any of them are approved.

Otic's product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the EMA, MHRA, FDA and other regulatory authorities. In the United States, these requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities, requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA, or other regulatory authorities, may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products and if Otic promotes its products beyond their approved indications, it may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with Otic's products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;

[Table of Contents](#)

- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that it submits;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of its products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Recently enacted and future legislation may increase the difficulty and cost for Otic to obtain marketing approval of and commercialize its product candidates and affect the prices Otic may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of its product candidates, restrict or regulate post-approval activities and affect its ability to profitably sell any product candidates for which Otic obtains marketing approval.

For example, in 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, (collectively, the "**PPACA**"). Among the provisions of the PPACA of importance to its potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

[Table of Contents](#)

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, while the healthcare reform agenda and policies of the new Trump administration are not fully known, it is possible that additional regulatory changes, as well as the repeal (in whole or in part) of the PPACA, could negatively affect insurance coverage and/or drug prices. These new laws may result in additional reductions in Medicare and other healthcare funding.

Otic expects that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that it receives for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent Otic from being able to generate revenue, attain profitability, or commercialize its products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Additionally, legislation has been introduced to repeal the PPACA. Otic cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of its product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject Otic to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may adversely affect its revenues, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, Otic may be required to conduct a clinical trial that compares the cost-effectiveness of its product candidate to other available therapies. If reimbursement of its products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, its business could be harmed, possibly materially.

Otic's relationships with customers and third-party payers will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose Otic to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers play a primary role in the recommendation and prescription of any product candidates for which Otic receives marketing approval. Otic's future arrangements with third-party payers and customers may expose Otic to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Otic markets, sell and distribute Otic's products for which Otic receives marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash

Table of Contents

- or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, require manufacturers of covered drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that Otic's business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that Otic's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Otic's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to Otic, Otic may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of Otic's operations. If any of the physicians or other providers or entities with whom Otic expects to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

If Otic fails to comply with environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could harm its business.

Otic may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair its preclinical or clinical

[Table of Contents](#)

development or production efforts. Otic's failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to the Commercialization of Otic's Product Candidates

Even if any of its product candidates receives marketing approval, Otic may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

If any of its product candidates receives marketing approval, Otic may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. In addition, physicians, patients and third-party payers may prefer other novel products to Otic's. If its product candidates do not achieve an adequate level of acceptance, Otic may not generate significant product revenues and Otic may not become profitable. The degree of market acceptance of Otic's product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- the ability to offer its products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of its marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;
- the ability to develop or partner with third-party collaborators to develop companion diagnostics;
- the prevalence and severity of any side effects; and
- any restrictions on the use of its products together with other medications.

If OP-01, OP-02 or future product candidates receives marketing approval and Otic, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, the ability to market the product could be compromised.

Clinical trials are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that Otic's clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, Otic, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- the product may be required to be recalled or changes to the way the product is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- the creation of a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;

[Table of Contents](#)

- additional restrictions may be imposed on the distribution or use of the product via a Risk Evaluation and Mitigation Strategy;
- Otic could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- Otic's reputation may suffer.

Any of these events could have a material and adverse effect on Otic's operations and business. The commercial prospects for Otic's product candidates may be harmed and its ability to generate revenues will be materially impaired.

Otic currently has no marketing and sales force. If Otic is unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell its product candidates, Otic may not be able to effectively market and sell its product candidates, if approved, or generate product revenues.

Otic currently does not have a marketing or sales team for the marketing, sales and distribution of any of its product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, Otic must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and Otic may not be successful in doing so. If its product candidates receive regulatory approval, Otic intends to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize its product candidates, which will be expensive and time-consuming and will require significant attention of its executive officers to manage. Any failure or delay in the development of its internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of its products that Otic obtains approval to market. With respect to the commercialization of all or certain of its product candidates, Otic may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment its own sales force and distribution systems or in lieu of its own sales force and distribution systems. If Otic is unable to enter into such arrangements when needed on acceptable terms or at all, Otic may not be able to successfully commercialize any of its product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If Otic is not successful in commercializing its product candidates, either on its own or through collaborations with one or more third parties, its future product revenue will suffer and Otic may incur significant additional losses.

Otic faces substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than Otic does.

The development and commercialization of new drug products is highly competitive. Otic faces competition with respect to its current product candidates, and will face competition with respect to any product candidates that Otic may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which Otic is developing its product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to Otic's approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for AOE, including many major pharmaceutical and biotechnology companies. Otic expects that OP-01 will face competition from numerous FDA-approved therapeutics, including CIPRODEX® and numerous other branded and generic ear anti-infectives.

[Table of Contents](#)

In OM, Otic expects that OP-02 will compete with antibiotics and a surgery where the tympanic membrane is perforated to improve drainage and ventilation of the middle ear (myringotomy or tympanostomy tube insertions). These therapies may continue to be the preferred therapies for treating OM.

In ETD, Otic expects that OP-02 will compete with a medical device that uses a small intranasal balloon inserted into the ET to treat persistent ETD in adults. Other similar and novel therapies may be developed and may become, or continue to be, the preferred therapies for treating ETD.

Otic's commercial opportunity could be reduced or eliminated if its competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that Otic may develop. In addition, its ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products.

Generic products are currently available, with additional products expected to become available over the coming years, potentially creating pricing pressure. If its product candidates achieve marketing approval, Otic expects that they will be priced at a significant premium over competitive generic products.

Many of the companies against which Otic is competing or against which Otic may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than Otic does. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of its competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with Otic in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, Otic's programs.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit its ability to market those products and decrease its ability to generate revenue.

The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments. Sales of Otic's product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of Otic's product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. If reimbursement is not available, or is available only to limited levels, Otic may not be able to successfully commercialize its product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow Otic to establish or maintain pricing sufficient to realize a sufficient return on its investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as Otic's, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and Otic believes the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of its product candidates. In many countries, the prices of medical products are subject to

Table of Contents

varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that Otic is able to charge for its product candidates. Accordingly, in markets outside the United States, the reimbursement for its products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for Otic's product candidates. Otic expects to experience pricing pressures in connection with the sale of any of its product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition, many private payers contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of its products.

Product liability lawsuits against Otic could cause it to incur substantial liabilities and to limit commercialization of any products that Otic may develop.

Otic faces an inherent risk of product liability exposure related to the testing of its product candidates in human clinical trials and will face an even greater risk if it commercially sells any products that it may develop. If Otic cannot successfully defend against claims that its product candidates or products caused injuries, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that Otic may develop;
- injury to its reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of its management to pursue its business strategy; and
- the inability to commercialize any products that Otic may develop.

Otic currently holds \$2 million in product liability insurance coverage in the aggregate, with a per incident limit of \$2 million, which may not be adequate to cover all liabilities that Otic may incur. Otic may need to increase its insurance coverage as it expands its clinical trials or if it commences commercialization of its product candidates. Insurance coverage is increasingly expensive. Otic may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Otic's Dependence on Third Parties

Future development collaborations may be important to Otic. If Otic is unable to enter into or maintain these collaborations, or if these collaborations are not successful, its business could be adversely affected.

For some of its product candidates, Otic may in the future determine to seek to collaborate with pharmaceutical and biotechnology companies for development of products. Otic faces significant competition in

[Table of Contents](#)

seeking appropriate collaborators. Otic's ability to reach a definitive agreement for any collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If Otic is unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, Otic may have to curtail the development of a product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential development schedule or reduce the scope of research activities, or increase its expenditures and undertake discovery or preclinical development activities at its own expense. If it fails to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, Otic may not be able to further develop its product candidates or continue to develop its product candidates, and its business may be materially and adversely affected.

Future collaborations Otic may enter into may involve the following risks:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by Otic, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Otic's products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than Otic's products;
- product candidates discovered in collaboration with Otic may be viewed by its collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of its product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the discovery, preclinical development or commercialization of product candidates, might lead to additional responsibilities for Otic with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend its intellectual property rights or intellectual property rights licensed to Otic or may use its proprietary information in such a way as to invite litigation that could jeopardize or invalidate its intellectual property or proprietary information or expose Otic to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose Otic to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, Otic could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Additionally, subject to its contractual obligations to Otic, if a collaborator is involved in a business combination, the collaborator might deemphasize or terminate the development of any of Otic's product candidates. If one of Otic's collaborators terminates its agreement with Otic, it may find Otic more difficult to attract new collaborators and Otic's perception in the business and financial communities could be adversely affected.

[Table of Contents](#)

If Otic's collaborations do not result in the successful development of products or product candidates, product candidates could be delayed and Otic may need additional resources to develop product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this proxy statement also apply to the activities of its collaborators.

Otic contracts with third parties for the manufacture of its product candidates for preclinical and clinical testing and expects to continue to do so for commercialization. This reliance on third parties increases the risk that Otic will not have sufficient quantities of its product candidates or products at an acceptable cost and quality, which could delay, prevent or impair its development or commercialization efforts.

Otic has utilized, and intends to continue utilizing, third parties to manufacture, package and distribute clinical supplies of Otic's drug candidates. Otic has no experience in manufacturing and does not have any manufacturing facilities. Currently, Otic has sole suppliers for one or more of its active pharmaceutical ingredients ("**API**"), and a different sole manufacturer for each of its product candidates. In addition, these materials are custom-made and available from only a limited number of sources. In particular, there may be a limited supply source for APIs for OP-02 or other future product candidates. Although Otic believes that Otic's third-party suppliers maintain a significant supply of APIs on hand, any sustained disruption in this supply could adversely affect Otic's operations. Otic does not have any long-term agreements in place with Otic's current API suppliers. If Otic is required to change manufacturers, Otic may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of Otic's products and product candidates in accordance with FDA requirements and Otic's specifications. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing approved product candidates could negatively affect Otic's sales revenues, as well as delay Otic's clinical trials.

Otic expects to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which its collaborators or it obtains marketing approval. Despite drug substance and product risk management, this reliance on third parties presents a risk that Otic will not have sufficient quantities of its product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair its development or commercialization efforts. Any performance failure on the part of its existing or future manufacturers of drug substance or drug products could delay clinical development or marketing approval. Otic does not currently have arrangements in place for redundant supply. If suppliers cannot supply Otic with its requirements, Otic may be required to identify alternative manufacturers, which would lead it to incur added costs and delays in identifying and qualifying any such replacement.

The formulation used in early studies is not a final formulation for commercialization. Additional, changes may be required by the FDA or other regulatory authorities on specifications and storage conditions. These may require additional studies, and may delay its clinical trials.

Otic also expects to rely on other third parties to store and distribute drug supplies for its clinical trials. Any performance failure on the part of its distributors could delay clinical development or marketing approval of its product candidates or commercialization of its products, producing additional losses and depriving it of potential product revenue.

Otic may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if Otic is able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of its proprietary information, including its trade secrets and know-how; and

[Table of Contents](#)

- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for Otic.

The third parties Otic relies on for manufacturing and packaging are also subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt Otic's clinical or commercialization activities. Third-party manufacturers may not be able to comply with cGMP, regulations or similar regulatory requirements outside the United States. Otic's failure, or the failure of its third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on Otic, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of its products. Additionally, macro-economic conditions may adversely affect these third parties, causing them to suffer liquidity or operational problems. If a key third-party vendor becomes insolvent or is forced to lay off workers assisting with Otic's projects, Otic's results and development timing could suffer.

Otic's product candidates and any products that Otic may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for Otic.

Otic's current and anticipated future dependence upon others for the manufacture of its product candidates or products may adversely affect its future profit margins and its ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Risks Related to Otic's Intellectual Property

If Otic is unable to obtain and maintain intellectual property protection for its technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, its competitors could develop and commercialize technology and products similar or identical to Otic's, and its ability to successfully commercialize its technology and products may be impaired.

Otic's success depends in large part on its ability to obtain and maintain patent protection in the European Union, the United States and other countries with respect to its proprietary technology and products. Otic seeks to protect its proprietary position by filing patent applications in the United States and abroad related to its novel technologies and product candidates. This patent portfolio includes issued patents and pending patent applications covering pharmaceutical methods of use.

The patent prosecution process is expensive and time-consuming, and Otic may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Otic may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that Otic will fail to identify patentable aspects of its discovery and preclinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, it may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that Otic licenses from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of its business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect its rights to the same extent as the laws of the United States. For example, India and China do not allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or

[Table of Contents](#)

in some cases not at all. Therefore, Otic cannot know with certainty whether it was the first to make the inventions claimed in its owned or licensed patents or pending patent applications, or that it was the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of its patent rights are highly uncertain. Otic's pending and future patent applications may not result in patents being issued which protect its technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the European Union, the United States and other countries may diminish the value of its patents or narrow the scope of its patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of its patent applications and the enforcement or defense of its issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the "*Leahy-Smith Act*"), was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office ("*USPTO*") recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of Otic's business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of its patent applications and the enforcement or defense of its issued patents, all of which could have a material adverse effect on its business and financial condition.

Moreover, Otic may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging its patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, its patent rights, allow third parties to commercialize its technology or products and compete directly with Otic, without payment to it, or result in its inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by its patents and patent applications is threatened, it could dissuade companies from collaborating with Otic to license, develop or commercialize current or future product candidates.

Even if Otic's owned and licensed patent applications issue as patents, they may not issue in a form that will provide it with any meaningful protection, prevent competitors from competing with it or otherwise provide it with any competitive advantage. Otic's competitors may be able to circumvent its owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and its owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit Otic's ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of Otic's technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, Otic's owned and licensed patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to Otic's.

The risks described elsewhere pertaining to its patents and other intellectual property rights also apply to the intellectual property rights that Otic licenses, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on its business. In some cases, Otic may not have control over the prosecution, maintenance or enforcement of the patents that it licenses, and its licensors may fail to take the steps that Otic believes are necessary or desirable in order to obtain, maintain and enforce the licensed patents. Any

[Table of Contents](#)

inability on Otic's part to protect adequately its intellectual property may have a material adverse effect on its business, operating results and financial position.

Obtaining and maintaining its patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and its patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. Otic has systems in place to remind it to pay these fees, and it employs an outside firm and relies on its outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Otic employs reputable law firms and other professionals to help it comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, Otic's competitors might be able to enter the market and this circumstance would have a material adverse effect on its business.

If Otic fails to comply with its obligations in the agreements under which it licenses intellectual property and other rights from third parties or otherwise experiences disruptions to its business relationships with its licensors, Otic could lose license rights that are important to its business.

Otic has acquired commercial rights to its OP-02 technology through a license agreement with Otodyne, Inc. and may in the future enter into other license agreements with third parties for other intellectual property rights or assets. These license agreements may impose various diligence, milestone payment, royalty, and other obligations on Otic. If Otic fails to comply with its obligations under these agreements, or it is subject to a bankruptcy, Otic may be required to make certain payments to the licensor, Otic may lose the exclusivity of its license, or the licensor may have the right to terminate the license, in which event Otic would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for Otic to develop its drug candidates than if Otic had developed the licensed technology internally.

In some cases, patent prosecution of Otic's licensed technology may be controlled solely by the licensor. If Otic's licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property Otic licenses from them, Otic could lose its rights to the intellectual property or its exclusivity with respect to those rights, and its competitors could market competing products using the intellectual property. In certain cases, Otic may control the prosecution of patents resulting from licensed technology. In the event Otic breaches any of its obligations related to such prosecution, Otic may incur significant liability to its licensing partners. If disputes over intellectual property and other rights that Otic has licensed prevent or impair its ability to maintain its current licensing arrangements on acceptable terms, Otic may be unable to successfully develop and commercialize the affected product candidates.

Otic may become involved in lawsuits to protect or enforce its patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Because competition in Otic's industry is intense, competitors may infringe or otherwise violate its issued patents, patents of its licensors or other intellectual property. To counter infringement or unauthorized use, Otic may be required to file infringement claims, which can be expensive and time-consuming. Any claims Otic asserts against perceived infringers could provoke these parties to assert counterclaims against it alleging that Otic infringes their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of Otic's is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the

[Table of Contents](#)

other party from using the technology at issue on the grounds that its patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of its patents at risk of being invalidated or interpreted narrowly. Otic may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require Otic to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of its confidential information could be compromised by disclosure.

Otic may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of Otic's products. It may be necessary for Otic to use the patented or proprietary technology of third parties to commercialize its products, in which case it would be required to obtain a license from these third parties on commercially reasonable terms, or its business could be harmed, possibly materially. Although Otic believes that licenses to these patents are available from these third parties on commercially reasonable terms, if it was not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, its business could be harmed, possibly materially.

Third parties may initiate legal proceedings alleging that Otic is infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of its business.

Otic's commercial success depends upon its ability, and the ability of its collaborators, to develop, manufacture, market and sell its product candidates and use its proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. Otic may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to its products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against Otic based on existing patents or patents that may be granted in the future.

If Otic is found to infringe a third party's intellectual property rights, Otic could be required to obtain a license from such third party to continue developing and marketing its products and technology. However, Otic may not be able to obtain any required license on commercially reasonable terms or at all. Even if Otic was able to obtain a license, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to it. Otic could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, Otic could be found liable for monetary damages, including treble damages and attorneys' fees if Otic is found to have willfully infringed a patent. A finding of infringement could prevent Otic from commercializing its product candidates or force it to cease some of its business operations, which could materially harm its business. Claims that Otic has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business.

If Otic is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.

In addition to seeking patents for some of its technology and product candidates, Otic also relies on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain its competitive position. Otic seeks to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as its employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Otic seeks to protect its confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with its employees and consultants, however, it cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent Otic enters into such agreements, any of

[Table of Contents](#)

these parties may breach the agreements and disclose its proprietary information, including its trade secrets, and Otic may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of its trade secrets were to be lawfully obtained or independently developed by a competitor, Otic would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with Otic. If any of its trade secrets were to be disclosed to or independently developed by a competitor, Otic's competitive position would be harmed.

Risks Related to Otic's Employee Matters, Managing Growth and Macroeconomic Conditions

Otic's future success depends on its ability to retain key executives and to attract, retain and motivate qualified personnel.

Otic is highly dependent on the product development, clinical and business development expertise of the principal members of its management, scientific and clinical team. Although Otic has entered into employment agreements with its key executive officers, each of them may terminate their employment with it at any time. Otic does not maintain "key person" insurance for any of its executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to Otic's success. The loss of the services of its executive officers or other key employees could impede the achievement of Otic's development and commercialization objectives and seriously harm Otic's ability to successfully implement its business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in Otic's industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and Otic may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Otic also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, Otic relies on consultants and advisors, including scientific and clinical advisors, to assist it in formulating its discovery and preclinical development and commercialization strategy. Otic's consultants and advisors may be employed by employers other than Otic and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to Otic. If Otic is unable to continue to attract and retain high quality personnel, its ability to pursue its growth strategy will be limited.

Otic expects to expand its research and development function, as well as corporate operations, and as a result, Otic may encounter difficulties in managing its growth, which could disrupt its operations.

Otic expects to experience significant growth in the number of its employees and the scope of its operations, particularly in the areas of drug development, regulatory affairs and, if any of its product candidates receives marketing approval, sales, marketing and distribution. To manage its anticipated future growth, Otic must continue to implement and improve its managerial, operational and financial systems, expand its facilities and continue to recruit and train additional qualified personnel. Due to its limited financial resources, Otic may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The expansion of its operations may lead to significant costs and may divert its management and business development resources. Any inability to manage growth could delay the execution of its business plans or disrupt its operations.

Otic may be subject to claims that its employees or directors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of Otic's employees and certain of Otic's directors were previously employed at universities or other biotechnology or pharmaceutical companies, including Otic's competitors or potential competitors.

[Table of Contents](#)

Although Otic tries to ensure that Otic's employees and directors do not use the proprietary information or know-how of others in their work for Otic, Otic may be subject to claims that Otic or these employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or director's former employer. Litigation may be necessary to defend against these claims. If Otic fails in defending any such claims, in addition to paying monetary damages, Otic may lose valuable intellectual property rights or personnel. Even if Otic is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Unfavorable global economic conditions could adversely affect its business, financial condition or results of operations.

Otic's results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to its business, including, its ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, where the United Kingdom's vote to leave the European Union has created additional economic uncertainty. A weak or declining economy could also strain its suppliers, possibly resulting in supply disruption. Any of the foregoing could harm its business and Otic cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact its business.

Otic's business and operations would suffer in the event of system failures.

Despite the implementation of security measures, its internal computer systems and those of its CROs, collaborators and third-parties on whom Otic relies are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, Otic has little or no control over the security measures and computer systems of its third-party collaborators. While Otic and, to its knowledge, its third-party collaborators have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in its operations or its third-party collaborators, it could result in a material disruption of its drug development programs. For example, the loss of research data could delay development of its product candidates and the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in its regulatory approval efforts and Otic may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to its data or applications, or inappropriate disclosure of confidential or proprietary information, Otic could incur liability and/or the further development of its product candidates could be delayed.

Risks Related to the Combined Company

Tokai and Otic expect the combined company will incur losses over the next several years and may never achieve or maintain profitability.

Tokai and Otic expect the combined company will continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses the combined company incurs may fluctuate significantly from quarter to quarter. Tokai and Otic anticipate that the combined company's expenses will increase substantially if and as it:

- continues clinical development of its product candidates;
- seeks to identify additional product candidates;
- acquires or in-licenses other products and technologies or enters into collaboration arrangements with regards to product discovery or development;
- develops manufacturing processes, conducts preclinical studies and initiates clinical trials for its product candidates;

Table of Contents

- seeks marketing approvals for any of its product candidates that successfully complete clinical trials;
- establishes a sales, marketing and distribution infrastructure to commercialize any products for which it may obtain marketing approval;
- maintains, expands and protects its intellectual property portfolio;
- hires additional personnel;
- adds operational, financial and management information systems and personnel, including personnel to support its product development and planned future commercialization efforts; and
- operates as a public company.

To become and remain profitable, the combined company must develop and eventually commercialize a product or products with significant market potential. This will require it to be successful in a range of challenging activities, including completing clinical trials of its product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which the combined company may obtain marketing approval. The combined company may never succeed in these activities and, even if it does, may never generate revenues that are significant or large enough to achieve profitability. If the combined company does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. The combined company's failure to become and remain profitable would decrease the value of the company and could impair its ability to raise capital, maintain its preclinical and clinical development efforts, expand its business or continue its operations and may require it to raise additional capital that may dilute the ownership interest of common stockholders. A decline in the value of the combined company could also cause stockholders to lose all or part of their investment.

The combined company will need substantial additional funding. If the combined company is unable to raise capital when needed, it would be compelled to delay, reduce or eliminate its product development programs or commercialization efforts.

The combined company expects its expenses to increase in parallel with its ongoing activities, particularly as it continues its preclinical and clinical development, identifies new clinical candidates and initiates clinical trials of, and seek marketing approval for, its product candidates. In addition, if the combined company obtains marketing approval for any of its product candidates, it expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. If the combined company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its preclinical and clinical development programs or any future commercialization efforts.

Based upon current operating plans, Otic expects the proceeds from the Equity Financing, along with net cash held by each of Tokai and Otic upon consummation of the Otic Transaction, will be able to fund the operations of the combined company into the second half of 2018. The combined company will require additional capital to complete the development and commercialization of OP-01 and OP-02, if approved, and may also need to raise additional funds to pursue other development activities related to additional product candidates. The combined company's funding needs may fluctuate significantly based on a number of factors, such as:

- the scope, progress, results and costs of compound discovery, preclinical development, laboratory testing and clinical trials for its product candidates;
- the extent to which it enters into additional collaboration arrangements with regard to product discovery, development, or acquires or in-licenses products or technologies;
- its ability to establish additional collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of its product candidates;

Table of Contents

- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of its product candidates for which Otic receives marketing approval;
- revenue, if any, received from commercial sales of its product candidates, should any of its product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing its intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and the combined company may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, its product candidates, if approved, may not achieve commercial success. The combined company's commercial revenues, if any, will be derived from sales of products that it does not expect to be commercially available for several years, if at all. Accordingly, the combined company will need to continue to rely on additional financing to achieve its business objectives. Adequate additional financing may not be available to it on acceptable terms, or at all.

Raising additional capital may cause dilution to the combined company's stockholders, restrict its operations or require it to relinquish rights to its technologies or product candidates.

Until such time, if ever, as the combined company can generate substantial product revenues, it expects to finance its cash needs through a combination of equity offerings and debt financings. The combined company does not have any committed external source of funds. To the extent that it raises additional capital through the sale of equity or convertible debt securities, the ownership interest of common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Tokai and Otic cannot be certain that additional funding will be available on acceptable terms, or at all. If the combined company is unable to raise additional funds when needed, it may be required to delay, limit, reduce or terminate its product development or future commercialization efforts.

Tokai and Otic expect the combined company's stock price to be volatile, and the market price of its common stock may drop following the transaction.

The market price of the common stock of the combined company following the transaction could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biopharmaceutical, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the common stock of the combined company to fluctuate include:

- the ability of the combined company to obtain regulatory approvals for OP-01, OP-02 or other product candidates, and delays or failures to obtain such approvals;
- failure of any of the combined company's product candidates, if approved, to achieve commercial success;
- issues in manufacturing the combined company's approved products, if any, or product candidates;
- the results of the combined company's current and any future clinical trials of its product candidates;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of the combined company's intellectual property rights or defend against the intellectual property rights of others;

Table of Contents

- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with potential products of the combined company;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover the combined company's common stock;
- general and industry-specific economic conditions that may affect the combined company's research and development expenditures;
- changes in the structure of healthcare payment systems; and
- period-to-period fluctuations in the combined company's financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company's profitability and reputation.

If securities analysts do not publish research or reports about the business of the combined company, or if they publish negative evaluations, the price of the combined company's common stock could decline.

The trading market for the combined company's common stock may be impacted by the availability or lack of research and reports that third-party industry or financial analysts publish about the combined company. There are many large, publicly traded companies active in the biopharmaceutical industry, which may mean it will be less likely that the combined company receives widespread analyst coverage. Furthermore, if one or more of the analysts who do cover the combined company downgrade its stock, its stock price would likely decline. If the combined company does not receive adequate coverage by reputable analysts that have an understanding of the combined company's business and industry, it could fail to achieve visibility in the market, which in turn could cause its stock price to decline.

After the Otic Transaction, the combined company's executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control all matters submitted to stockholders for approval.

Upon the closing of the Otic Transaction and the related Equity Financing, the combined company's executive officers and directors, combined with its affiliates are expected to, in the aggregate, beneficially own shares representing approximately % of its capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to the combined company's stockholders for approval, as well as its management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of its assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench its management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving the combined company that other stockholders may desire.

[Table of Contents](#)

The failure to integrate successfully the businesses of Otic and Tokai in the expected timeframe could adversely affect the future results of the combined company following the completion of the transaction.

The success of the transaction will depend, in large part, on the ability of the combined company following the completion of the transaction to realize the anticipated benefits from combining the businesses of Tokai and Otic. The continued operation of the two companies will be complex.

The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company's failure to achieve some or all of the anticipated benefits of the transaction.

Potential difficulties that may be encountered in the integration process include the following:

- using the combined company's cash and other assets efficiently to develop the business of Otic;
- appropriately managing the liabilities of the combined company;
- potential unknown or currently unquantifiable liabilities associated with the transaction and the operations of the combined company;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the transaction; and
- performance shortfalls at one or both of the companies as a result of the diversion of management's attention caused by completing the transaction and integrating the companies' operations.

The combined company will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

The combined company will incur significant legal, accounting and other expenses that Otic did not incur as a private company, including costs associated with public company reporting requirements. The combined company will also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act and rules and regulations promulgated by the SEC and NASDAQ. These rules and regulations are expected to increase the combined company's legal and financial compliance costs and to make some activities more time-consuming and costly. These rules and regulations may also make it difficult and expensive for the combined company to obtain directors' and officers' liability insurance. As a result, it may be more difficult for the combined company to attract and retain qualified individuals to serve on the combined company's board of directors or as executive officers of the combined company, which may adversely affect investor confidence in the combined company and could cause the combined company's business or stock price to suffer.

If the combined company fails to establish and maintain proper and effective internal control over financial reporting, its operating results and its ability to operate the combined company's business could be harmed.

Ensuring that the combined company will have adequate internal financial and accounting controls and procedures in place so that it can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP.

Through the fiscal year ended December 31, 2015, Otic's financial statements have been audited in accordance with generally accepted auditing standards in Israel. In connection with the auditor's report included with this filing, the consolidated financial statements for the years ended December 31, 2015 and 2014 were audited in accordance with generally accepted auditing standards in the United States. Otic's consolidated financial statements for the fiscal year ended December 31, 2016 will also be audited in accordance with generally accepted auditing standards in the United States.

[Table of Contents](#)

Beginning with the fiscal year ended December 31, 2017, Otic's financial statements will be audited in accordance with the standards of the Public Company Accounting Oversight Board (United States). In addition, Otic will be required to be compliant with public company internal control requirements mandated under Section 302 and 906 of the Sarbanes-Oxley Act. Otic will be implementing measures designed to improve its internal controls over financial reporting, including the hiring of accounting personnel and establishing new accounting and financial reporting procedures to establish an appropriate level of internal controls over financial reporting. However, Otic is still in the process of implementing these measures and cannot provide assurances that it or the combined company will be successful in doing so. If Otic or the combined company is unable to successfully implement internal controls over financial reporting, the accuracy and timing of its financial reporting, and its stock price, may be adversely affected and it may be unable to maintain compliance with the applicable stock exchange listing requirements.

Implementing any appropriate changes to Otic's or the combined company's internal controls may distract the officers and employees of Otic or the combined company, entail substantial costs to modify its existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of the internal controls of the combined company, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase operating costs and harm the business. In addition, investors' perceptions that the internal controls of Otic or the combined company are inadequate or that it is unable to produce accurate financial statements on a timely basis may harm the stock price of the combined company.

Provisions in the combined company's corporate charter documents and under Delaware law could make an acquisition of the combined company, which may be beneficial to its stockholders, more difficult and may prevent attempts by its stockholders to replace or remove the combined company's current management.

Provisions in the combined company's corporate charter and the combined company's bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the combined company that stockholders may consider favorable, including transactions in which the combined company's stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of the combined company's common stock, thereby depressing the market price of its common stock. In addition, because the board of directors is responsible for appointing the members of the combined company's management team, these provisions may frustrate or prevent any attempts by stockholders to replace or remove the current management by making it more difficult for stockholders to replace members of the board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of the combined company's directors to be changed only by resolution of its board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to the combined company's board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by the combined company's stockholders by written consent;
- limit who may call stockholder meetings;
- authorize the board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the combined company's board of directors; and

[Table of Contents](#)

- require the approval of the holders of at least 75% of the votes that all the combined company's stockholders would be entitled to cast to amend or repeal certain provisions of the combined company's charter or bylaws.

Moreover, because the combined company is incorporated in Delaware, the combined company is governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of its outstanding voting stock from merging or combining with the combined company for a period of three years after the date of the transaction in which the person acquired in excess of 15% of the combined company's outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Tokai and Otic do not anticipate that the combined company will pay any cash dividends in the foreseeable future.

The current expectation is that the combined company will retain its future earnings to fund the development and growth of the combined company's business. As a result, capital appreciation, if any, of the common stock of the combined company will be the sole source of gain, if any, for any stockholders for the foreseeable future.

The Otic Transaction will result in changes to the combined company's board of directors that may affect the combined company's business strategy and operations.

The composition of the combined company's board of directors will change as described in more detail in the section of this proxy statement entitled "*Terms of the Share Purchase Agreement—Directors and Officers of Tokai Following the Otic Transaction*" beginning on page 99. The newly comprised board of directors of the combined company may affect business strategies and operating decisions with respect to the combined company that may have an adverse impact on the combined company's business, financial condition and results of operations following the completion of the transaction.

If the Otic Transaction is completed, the future success of the combined company depends on its ability to retain key members of its management team.

If the Otic Transaction is completed, the combined company will be highly dependent on principal members of its management team, which will include Mr. Flesher, Ms. Ocampo and Dr. Turkel of Otic as described in more detail in the section of this proxy statement entitled "*Terms of the Share Purchase Agreement—Directors and Officers of Tokai Following the Otic Transaction*" beginning on page 99. The loss of the services of any member of the combined company's management team may adversely impact the achievement of its objectives. Although Otic has entered into employment agreements with Mr. Flesher, Ms. Ocampo and Dr. Turkel, any of them could leave the combined company's employment at any time. The inability to recruit or the loss of the services of any executive or key employee may impede the progress of the combined company's research, development and company objectives.

The success of the combined company will also depend on pre-existing relationships with third parties, which relationships may be affected by the Otic Transaction. Any adverse changes in these relationships could adversely affect the combined company's business, financial condition or results of operations.

The combined company's success will be dependent on the ability to maintain and renew relationships with pre-existing third-party relationships. There can be no assurance that the business of the combined company will be able to maintain pre-existing business relationships, or enter into or maintain new business relationships, on acceptable terms, if at all. The failure to maintain important pre-existing third-party relationships could have a material adverse effect on the business, financial condition or results of operations of the combined company.

The pro forma financial statements are presented for illustrative purposes only and may not be an indication of the combined company's financial condition or results of operations following the completion of the transaction.

The pro forma financial statements contained in this proxy statement are presented for illustrative purposes only and may not be an indication of the combined company's financial condition or results of

[Table of Contents](#)

operations following the Otic Transaction for several reasons. The pro forma financial statements have been derived from the historical financial statements of Tokai and Otic and adjustments and assumptions have been made regarding the combined company after giving effect to the transaction. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with accuracy. Moreover, the pro forma financial statements do not reflect all costs that are expected to be incurred by the combined company in connection with the transaction. For example, the impact of any incremental costs incurred in integrating the two companies is not reflected in the pro forma financial statements. As a result, the actual financial condition of the combined company following the Otic Transaction may not be consistent with, or evident from, these pro forma financial statements. The assumptions used in preparing the pro forma financial information may not prove to be accurate, and other factors may affect the combined company's financial condition following the transaction. The pro forma financial statements can be found in the section entitled "Unaudited Pro Forma Combined Financial Information," beginning on page 171 of this proxy statement.

Future sales of shares by existing stockholders could cause the combined company's stock price to decline.

If existing stockholders of Tokai and Otic sell, or indicate an intention to sell, substantial amounts of the combined company's common stock in the public market after the post-transaction lock-up and other legal restrictions on resale discussed in this proxy statement lapse, the trading price of the common stock of the combined company could decline. Upon completion of the Otic Transaction and the Equity Financing, without giving effect to the proposed reverse stock split, the combined company is expected to have approximately million shares outstanding, including shares issued in connection with the Equity Financing. As of immediately following the closing of the Otic Transaction, without giving effect to the proposed reverse stock split, approximately 22.6 million shares of common stock will be freely tradable, without restriction, in the public market.

The Share Purchase Agreement contains a lock-up covenant from the Otic shareholders, which provides that for 180 days following the closing of the Otic Transaction, no Otic shareholder shall offer, sell, or otherwise dispose of, directly or indirectly, any securities of Tokai, or otherwise enter into a transaction that would have similar effect. Assuming a registration statement covering the resale of the shares of Tokai common stock issuable in connection with the Equity Financing is in effect and without giving effect to the proposed reverse stock split, up to an additional approximately million shares of common stock will be eligible for sale in the public market, including shares issued in connection with the Equity Financing. Further, shares held by directors, executive officers of the combined company and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

Even if the combined company's product candidates are successful in clinical trials, the combined company may not be able to successfully commercialize them, which may adversely affect the combined company's future revenues and financial condition.

Otic has dedicated substantially all of its resources to the research and development of its product candidates. At present, Otic is focusing its resources on its primary product candidates, OP-01 and OP-02, which are currently in the early stages of clinical development. The combined company may not develop any other product candidates.

Prior to commercialization, each product candidate will require significant additional research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons, including that they may:

- be found ineffective or cause harmful side effects during clinical trials;
- fail to receive necessary regulatory approvals;
- be difficult to manufacture on a large scale;

[Table of Contents](#)

- be uneconomical to produce;
- fail to achieve market acceptance; or
- be precluded from commercialization by proprietary rights of third parties.

The combined company's product development efforts or the combined company's collaborative partners' efforts may not be successfully completed for any product candidate, and the combined company may not obtain any required regulatory approvals or successfully commercialize a product candidate even if clinical development for such product candidate is successfully completed. Any products, if introduced, may not be successfully marketed nor achieve customer acceptance, which may adversely affect the combined company's future revenues and financial condition.

Because the merger will result in an ownership change under Section 382 of the Internal Revenue Code, or the Code, for Tokai, Tokai's pre-merger net operating loss carryforwards and certain other tax attributes may be subject to limitations. The net operating loss carryforwards and other tax attributes of Otic and of the combined company may also be subject to limitations as a result of ownership changes.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The transaction will result in an ownership change for Tokai and, accordingly, Tokai's net operating loss carryforwards and certain other tax attributes may be subject to limitations (or disallowance) on their use after the transaction. Otic's net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the transaction. Additional ownership changes in the future could result in additional limitations on Tokai's, Otic's and the combined company's net operating loss carryforwards. Consequently, even if the combined company achieves profitability, it may not be able to utilize a material portion of Tokai's, Otic's or the combined company's net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Risks Related to the Proposed Reverse Stock Split

The reverse stock split may not increase the combined company's stock price over the long term and could potentially lead to a decrease in the combined company's overall market capitalization.

The principal purpose of the reverse stock split is to increase the per share market price of Tokai common stock. However, the reverse stock split may not accomplish this objective for any meaningful period of time. While it is expected that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of Tokai common stock, the reverse stock split may not increase the market price of Tokai common stock by a multiple of the proposed reverse stock split ratio, or result in any permanent or sustained increase in the market price of Tokai common stock, which is dependent upon many factors, including the combined company's business and financial performance, general market conditions, and prospects for future success. Thus, while the stock price of the combined company might meet the initial listing requirements for NASDAQ initially, it may not continue to meet the continued listing requirements for NASDAQ.

Should the market price of the combined company's common stock decline after the reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the reverse stock split. A reverse stock split may be viewed negatively by the market and, consequently, can lead to a decrease in the combined company's overall market capitalization.

[Table of Contents](#)

The reverse stock split may decrease the liquidity of the combined company's common stock.

Although the Tokai board of directors believes that the anticipated increase in the market price of the combined company's common stock could encourage interest in its common stock and possibly promote greater liquidity for its stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for Tokai common stock. Additionally, the reverse stock split may result in some Tokai stockholders owning "odd lots" of fewer than 100 shares on a post-split basis. Such stockholders would be able to sell the odd lots, but odd lot sales may be more difficult to sell or result in higher transaction costs per share than "board lot" sales, which are sales of even multiples of 100 shares.

**CAUTIONARY STATEMENT REGARDING
FORWARD-LOOKING INFORMATION**

This proxy statement and information included in oral statements or other written statements made or to be made by Tokai or on Tokai's behalf may contain predictions, estimates and other information that may be considered "forward-looking statements," within the meaning of the Private Securities Litigation Reform Act of 1995 (which is applicable to Tokai, but not Otic, because Tokai, unlike Otic, is a public company subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"). Such forward-looking statements include, without limitation: statements regarding the structure, timing and completion of the proposed transaction; Tokai's continued listing on The NASDAQ Global Market prior to and after the proposed transaction; expectations regarding the capitalization, cash balances and working capital, resources and ownership structure of the company after the transaction; expectations regarding the sufficiency of the company's resources to fund the advancement of any development program or the completion of any clinical trial; the nature, strategy and focus of the company after the transaction; the safety, efficacy and projected development timeline and commercial potential of any product candidates; and the expectations regarding voting by Tokai stockholders. You can typically identify forward-looking statements by the use of forward-looking terminology including "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "pro forma," "estimate," "project," "continue," "potential," "forecast" or "anticipate" or the negative of these words and phrases or other variations of these words and phrases or comparable terminology. Stockholders are cautioned that any forward-looking statements are not guarantees of future performance. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: risks and uncertainties associated with stockholder approval of and the ability to consummate the proposed transaction; whether the anticipated cash resources will be sufficient to fund operations for the period anticipated and to conduct the anticipated studies; whether the necessary approvals to commence clinical trials of Otic's product candidates can be obtained on a timely basis or at all; and whether the results of clinical trials will warrant submission for regulatory approval, any such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies and, if any of such product candidates obtains such approval, it will be successfully distributed and marketed.

For a further discussion of the factors that may cause Tokai or the combined company's actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, or for a discussion of risks associated with the ability of Tokai and Otic to complete the Otic Transaction and the effect of the Otic Transaction on the business of Tokai and the combined company, see the section entitled "*Risk Factors*," beginning on page 29 of this proxy statement.

If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Tokai, Otic or the combined company could differ materially from the forward-looking statements. All forward-looking statements in this proxy statement are current only as of the date on which the statements were made. Tokai and Otic expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

INFORMATION ABOUT THE SPECIAL MEETING

General

This proxy statement is being provided to Tokai stockholders as part of a solicitation of proxies by the board of directors of Tokai for use at a special meeting of Tokai stockholders and at any adjournments or postponements of such special meeting. This proxy statement provides Tokai stockholders with information about the special meeting and should be read carefully in its entirety.

Date, Time and Place

Tokai will hold the special meeting on _____, 2017, at _____ local time, at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109, unless postponed to a later date. On or about _____, 2017, Tokai commenced mailing this proxy statement and the enclosed form of proxy to Tokai's stockholders entitled to vote at Tokai's special meeting.

Purposes of the Tokai Special Meeting

The purposes of the special meeting are to consider and vote upon the following:

Proposal 1: to approve the related issuances of Tokai common stock pursuant to (i) the terms of the Share Purchase Agreement and (ii) the terms of the Tokai Stock Purchase Agreement (the "**Share Issuances Proposal**");

Proposal 2: to approve and adopt an amendment to Tokai's Amended and Restated Certificate of Incorporation to effect a reverse stock split of Tokai common stock, at a ratio ranging from _____:1 to _____:1, as determined by the Tokai board of directors, which split may be effected at any time within _____ months of the date of the special meeting (the "**Reverse Stock Split Proposal**");

Proposal 3: to adjourn the special meeting to solicit additional votes to approve the Share Issuances Proposal or the Reverse Stock Split Proposal, if necessary or appropriate (the "**Adjournment Proposal**"); and

Any other business that may properly come before the special meeting and any adjournments or postponements thereof.

Only the approval of Proposal 1 (the Share Issuances Proposal) is required for completion of the Otic Transaction.

Recommendation of the Tokai Board of Directors

- The Tokai board of directors has determined and believes that the related issuances of Tokai common stock pursuant to the Share Purchase Agreement and pursuant to the Tokai Stock Purchase Agreement are fair to, advisable, and in the best interests of, Tokai and its stockholders and has approved such items. The Tokai board of directors recommends that Tokai stockholders vote "FOR" the Share Issuances Proposal.
- The Tokai board of directors has determined and believes that it is fair to, advisable, and in the best interests of, Tokai and its stockholders to effect a reverse stock split at a ratio ranging from _____:1 to _____:1, as determined by the Tokai board of directors, which split may be effected at any time within _____ months of the date of the special meeting. The Tokai board of directors recommends that Tokai stockholders vote "FOR" the Reverse Stock Split Proposal.
- The Tokai board of directors has determined and believes that adjourning the special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the Share

[Table of Contents](#)

Issuances Proposal or the Reverse Stock Split Proposal is fair to, advisable, and in the best interests of, Tokai and its stockholders and has approved and adopted the proposal. The Tokai board of directors recommends that Tokai stockholders vote “FOR” the Adjournment Proposal.

Stockholders Entitled to Vote; Record Date

To be entitled to vote, you must have been a stockholder of record at the close of business on _____, 2017, the record date for the special meeting. There were _____ shares of Tokai common stock outstanding and entitled to vote at the special meeting as of the record date.

Each share of Tokai common stock that you own as of the record date will entitle you to one vote on each matter considered at the special meeting. See the section entitled “*Security Ownership of Certain Beneficial Owners and Management of Tokai*” beginning on page 169 of this proxy statement for information regarding the stock ownership of persons known to the management of Tokai to be the beneficial owners of more than 5% of the outstanding shares of Tokai common stock and of Tokai’s directors and officers.

Quorum and Broker Non-Votes

A majority of Tokai shares of common stock outstanding at the record date must be present in person or represented by proxy to hold the special meeting. This is called a quorum. For purposes of determining whether a quorum exists, Tokai counts as present any shares that are voted over the Internet, by telephone or by completing and submitting a proxy card by mail or that are represented in person at the meeting. Further, for purposes of establishing a quorum, Tokai will count as present shares that a stockholder holds even if the stockholder votes to abstain or only votes on one of the proposals. In addition, Tokai will count as present shares held in “street name” by brokers who indicate on their proxies that they do not have authority to vote those shares. If a quorum is not present, Tokai expects to adjourn the special meeting until it obtains a quorum.

Banks, brokerage firms and other nominees who hold shares for the accounts of their clients may vote such shares either as directed by their clients or in their own discretion on “discretionary” matters. None of the Share Issuances Proposal, the Reverse Stock Split Proposal or the Adjournment Proposal is a “discretionary” matter. When a broker does not receive instructions from a non-record owner on how to vote shares with respect to a “non-discretionary” matter, a broker “non-vote” occurs. Broker “non-votes” will be treated as present for purposes of determining whether a quorum is present, but will not be counted as votes cast “FOR” or “AGAINST” any matter.

Required Vote

The votes required for each proposal are as follows:

Proposal 1 (Share Issuances Proposal). Approval of the Share Issuances Proposal requires the affirmative vote of a majority of the shares of Tokai common stock, present in person or represented by proxy and entitled to vote on the subject matter. Broker non-votes and abstentions will have no effect on Proposal 1 (Share Issuances Proposal).

Proposal 2 (Reverse Stock Split Proposal). Approval of the Reverse Stock Split Proposal requires the affirmative vote of a majority of the shares of Tokai common stock outstanding and entitled to vote at the special meeting. Because the vote on the Reverse Stock Split Proposal is based on the total number of shares outstanding, rather than the number of actual votes cast, abstentions and “broker non-votes” will have the same effect as voting against Proposal 2 (Reverse Stock Split Proposal).

Proposal 3 (Adjournment Proposal). Approval of the Adjournment Proposal requires the affirmative vote of a majority of the shares of Tokai common stock, present in person or represented by proxy and entitled to vote on the subject matter. Broker non-votes and abstentions will have no effect on Proposal 3 (Adjournment Proposal).

[Table of Contents](#)

Each of the Share Issuances Proposal, Reverse Stock Split Proposal and Adjournment Proposal is an independent proposal; none of the foregoing is conditioned upon the approval of any other proposal. The approval of the Share Issuances Proposal is required to consummate the Otic Transaction. The Otic Transaction may be consummated regardless of whether the Tokai stockholders approve or do not approve the Reverse Stock Split Proposal or the Adjournment Proposal. If the Share Issuances Proposal is not approved and the Otic Transaction is not consummated, Tokai's board of directors may determine to proceed with the reverse stock split if the Reverse Stock Split Proposal is approved.

Voting by Stockholders

If you are the "record holder" of your shares, meaning that your shares are registered in your name in the records of Tokai's transfer agent, Continental Stock Transfer & Trust Company, you may vote your shares at the meeting in person or by proxy as follows:

1. **Over the Internet:** To vote over the Internet, please go to the following website: www.proxypush.com/tkai, and follow the instructions at that site for submitting your proxy electronically. If you vote over the Internet, you do not need to complete and mail your proxy card or vote your proxy by telephone. You must specify how you want your shares voted or your Internet vote cannot be completed, and you will receive an error message. You must submit your Internet proxy before 11:59 p.m., Eastern Time, on _____, 2017, the day before the special meeting, for your proxy to be valid and your vote to count.
2. **By Telephone:** To vote by telephone, please call (866) 206-4382, and follow the instructions provided on the proxy card. If you vote by telephone, you do not need to complete and mail your proxy card or vote your proxy over the Internet. You must specify how you want your shares voted and confirm your vote at the end of the call or your telephone vote cannot be completed. You must submit your telephonic proxy before 11:59 p.m., Eastern Time, on _____, 2017, the day before the special meeting, for your proxy to be valid and your vote to count.
3. **By Mail:** To vote by mail, you must mark, sign and date the proxy card and then mail the proxy card in accordance with the instructions on the proxy card. If you vote by mail, you do not need to vote your proxy over the Internet or by telephone. Mediant Communications, Inc. must receive the proxy card not later than _____, 2017, the day before the special meeting, for your proxy to be valid and your vote to count. If you return your proxy card but do not specify how you want your shares voted on any particular matter, they will be voted in accordance with the recommendations of the Tokai board of directors.
4. **In Person at the Meeting:** If you attend the special meeting, you may deliver your completed proxy card in person or you may vote by completing a ballot, which Tokai will provide to you at the meeting.

If your shares are held in "street name," meaning they are held for your account by an intermediary, such as a broker, then you are deemed to be the beneficial owner of your shares and the broker that actually holds the shares for you is the record holder and is required to vote the shares it holds on your behalf according to your instructions. The proxy materials, as well as voting and revocation instructions, should have been forwarded to you by the broker that holds your shares. In order to vote your shares, you will need to follow the instructions that your broker provides you. Many brokers solicit voting instructions over the Internet or by telephone.

If you do not give instructions to your broker, your broker will not be able to vote your shares with respect to "non-discretionary" items. The Share Issuances Proposal, the Reverse Stock Split Proposal and the Adjournment Proposal are each "non-discretionary" items. Accordingly, if you do not give your broker voting instructions on any of these proposals, your broker may not vote your shares with respect to such matter and your shares will be counted as "broker non-votes" with respect to such proposal. A "broker non-vote" occurs when shares held by a broker are not voted with respect to a particular proposal because the broker does not have or did not exercise discretionary authority to vote on the matter and has not received voting instructions from its clients.

[Table of Contents](#)

Regardless of whether your shares are held in street name, you are welcome to attend the meeting. You may not vote shares held in street name in person at the meeting, however, unless you obtain a legal proxy, executed in your favor, from the holder of record (i.e., your broker). A legal proxy is not the form of proxy included with this proxy statement.

All properly executed proxies that are not revoked will be voted at the special meeting and at any adjournments or postponements of the special meeting in accordance with the instructions contained in the proxy. If a holder of Tokai common stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted "FOR" the Share Issuances Proposal; "FOR" the Reverse Stock Split Proposal; and "FOR" the Adjournment Proposal in accordance with the recommendation of the Tokai board of directors.

Revocation of Proxies

Tokai stockholders of record, other than those Tokai stockholders who have executed the Support Agreement, may change their vote at any time before their proxy is voted at the special meeting in any of the following ways.

If your shares are registered directly in your name, you may revoke your proxy and change your vote at any time before the vote is taken at the special meeting. To do so, you must do one of the following:

1. Vote over the Internet or by telephone as instructed above. Only your latest Internet or telephone vote is counted.
2. Sign and return a new proxy card. Only your latest dated and timely received proxy card will be counted.
3. Attend the special meeting and vote in person as instructed above. Attending the special meeting will not alone revoke your Internet vote, telephone vote or proxy card submitted by mail, as the case may be.
4. Give Tokai's corporate secretary written notice before or at the meeting that you want to revoke your proxy.

If your shares are held in "street name," you may submit new voting instructions by contacting your broker or other nominee. You may also vote in person at the special meeting if you obtain a legal proxy as described in the answer above.

Voting by Tokai's Directors, Executive Officers and Certain Stockholders

As of December 31, 2016, certain directors and executive officers of Tokai and entities associated with Apple Tree Partners ("*Apple Tree*"), Tokai's largest stockholder, collectively owned approximately 36.3% of the outstanding shares of Tokai stock entitled to vote at the Tokai special meeting. These directors, executive officers of Tokai and Apple Tree are subject to a Support Agreement. Each stockholder that entered into the Support Agreement has agreed, solely in its capacity as an equityholder, to vote all of the shares of Tokai common stock held by such stockholder in favor of the issuance of Tokai common stock in the Otic Transaction and against any "acquisition proposal," as defined in the Share Purchase Agreement and described in the section entitled, "*Terms of the Share Purchase Agreement—No Solicitation; Third Party Competing Proposal*," beginning on page 101 of this proxy statement. As of _____, 2017, Tokai is not aware of any affiliate of Otic owning any shares of Tokai common stock entitled to vote at the Tokai special meeting.

Solicitation of Proxies

Tokai will bear the cost of soliciting proxies. In addition to solicitation by mail, Tokai's directors, officers and employees may solicit proxies by telephone, e-mail, facsimile, and in person without additional

[Table of Contents](#)

compensation. Tokai may reimburse brokers or persons holding stock in their names, or in the names of their nominees, for their expenses in sending proxies and proxy material to beneficial owners.

No Appraisal Rights

Holders of Tokai common stock are not entitled to appraisal rights under Delaware law with respect to any of the proposals to be voted on at the special meeting. For more information about appraisal rights, see the provisions of Section 262 of the DGCL.

Householding

Some brokers and other nominee record holders may be “householding” Tokai’s proxy materials. This means a single notice and, if applicable, the proxy materials, will be delivered to multiple stockholders sharing an address unless contrary instructions have been received. Tokai will promptly deliver a separate copy of the notice and, if applicable, the proxy materials, to you if you write or call Tokai at Tokai Pharmaceuticals, Inc., 255 State Street, 6th Floor, Boston, Massachusetts 02109, Attention: Investor Relations, telephone: (617) 225-4305. If you would like to receive separate copies of Tokai’s proxy materials and annual reports in the future, or if you are receiving multiple copies and would like to receive only one copy for your household, you should contact your bank, broker, or other nominee record holder, or you may contact Tokai at the above address and telephone number.

Tabulation of Votes

The votes will be counted, tabulated and certified by Mediant Communications, Inc.

Adjournments and Postponements

If at the special meeting, the Tokai board of directors determines that it is necessary or appropriate to seek to adjourn or postpone the special meeting to seek additional proxies to approve any of the Share Issuances Proposal or the Reverse Stock Split Proposal, then the Tokai board of directors will move to vote on the Adjournment Proposal. If the stockholders approve the Adjournment Proposal, Tokai may adjourn or postpone the meeting. If the special meeting is adjourned or postponed, Tokai is not required to give notice of the time and place of the adjourned or postponed meeting if it is to take place within 30 days and if the time and place of the adjourned or postponed meeting are announced at the special meeting, unless the Tokai board of directors fixes a new record date for the special meeting.

Attending the Special Meeting

Regardless of whether your shares are held in street name, you are welcome to attend the meeting. You may not vote shares held in street name in person at the meeting, however, unless you obtain a legal proxy, executed in your favor, from the holder of record (i.e., your broker). A legal proxy is not the form of proxy included with this proxy statement.

THE OTIC TRANSACTION

The Transaction Structure

Upon the terms and subject to the conditions set forth in the Share Purchase Agreement, Tokai will acquire all of the ordinary and preferred shares of Otic in exchange for the issuance to the Sellers of a specified number of shares of Tokai common stock and will assume all outstanding share options and warrants of Otic.

Based on the outstanding share capital of Otic as of the date of the Share Purchase Agreement and the shares issuable upon exercise of warrants to purchase shares of Otic and the conversion of certain outstanding debt facilities of Otic into shares of Otic that are expected to be exercised or converted prior to the closing of the Otic Transaction, Tokai expects to issue _____ shares of Tokai common stock in the Otic Transaction. If all of Otic's outstanding options and warrants are exercised prior to closing, Tokai will issue a total of 36,911,631 shares of Tokai common stock in the Otic Transaction. Following the closing of the Otic Transaction, the stockholders of Otic are expected to hold approximately 60% of the outstanding shares of Tokai common stock, excluding for this purpose the effect on ownership of the issuance of shares in the Equity Financing. The relative percentage ownership of the combined company was derived using a stipulated value of Otic of approximately \$50.0 million and of Tokai of approximately \$33.0 million.

The issuance of Tokai common stock to the Sellers will be issued in transactions exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, and Regulation D or Regulation S promulgated thereunder and may not be offered or sold by the holders of those shares absent registration or an applicable exemption from registration requirements.

Consideration

The number of shares to be issued to Otic shareholders in total is based on an exchange ratio of 4.255 shares of Tokai common stock for each Otic ordinary and preferred share, as described in the section entitled "*Terms of the Share Purchase Agreement—Exchange Ratio*," beginning on page 98 of this proxy statement. The relative percentage ownership of the combined company was derived using a stipulated value of Otic of approximately \$50.0 million and of Tokai of approximately \$33.0 million and therefore following the closing of the Otic Transaction, the stockholders of Otic are expected hold approximately 60% of the outstanding shares of Tokai common stock.

Additionally, in connection with the Otic Transaction, Tokai has entered into the Tokai Stock Purchase Agreement dated January _____, 2017 with Otic and certain purchasers set forth therein pursuant to which the purchasers have agreed to purchase _____ shares of Tokai common stock at a price of \$ _____ per share. The Tokai Stock Purchase Agreement provides that the purchase and sale of the Tokai common stock will occur immediately following the closing of the Otic Transaction.

Effect of the Otic Transaction on Otic Share Options, Otic Warrants and Tokai Stock Options

Otic Share Options and Otic Warrants

Pursuant to the Share Purchase Agreement, at closing Tokai will assume the then outstanding share option awards and warrants of Otic (other than warrants of Otic that are exercised in connection with the Otic Transaction). Each of these options and warrants will be adjusted to reflect a ratio of shares of Tokai common stock for each Otic share. Accordingly, at closing, each of Otic's outstanding share option awards and warrants will become exercisable, as the case may be, for or into _____ shares of Tokai common stock for each Otic share it was previously exercisable for into, at a correspondingly adjusted exercise price, provided that the exercise price of such stock options and warrants will be rounded down to the nearest whole share and the exercise prices will be rounded up to the nearest cent, and no cash payment will be made in respect of such

[Table of Contents](#)

rounding. After giving effect to the ratio, and assuming no exercise of, or other change in, the number of outstanding share option awards and warrants of Otic, Tokai will assume options to purchase _____ shares of Tokai common stock at a weighted average exercise price of \$ _____ per share and warrants to purchase _____ shares of Tokai common stock at a weighted average exercise price of \$ _____ per share. If all of these options and warrants were exercised prior to the closing of the Otic Transaction, Tokai would issue 36,911,631 shares of common stock and the Otic shareholders would own approximately 62% of the outstanding shares of Tokai common stock.

Tokai Options

Upon closing of the Otic Transaction, all of Tokai's outstanding stock options will remain outstanding and in effect. Tokai's board of directors has determined that the Otic Transaction constitutes a change in control for purpose of Tokai's stock options. As a result, if any holder of Tokai stock options (other than Tokai's non-employee directors) is terminated without cause or resigns for good reason following the closing, such holder's stock options will immediately vest in full. Stock options held by Tokai's non-employee directors will vest in full immediately upon the closing.

Expected Timing of the Otic Transaction

Unless the Share Purchase Agreement is earlier terminated pursuant to its terms, the Otic Transaction will be consummated, as promptly as practicable, but in no event later than the second business day, following the satisfaction or waiver of the conditions to the consummation of the Otic Transaction, including stockholder approval of the Share Issuances Proposal at this special meeting, as described in the section entitled "*Terms of the Share Purchase Agreement—Conditions to the Consummation of the Otic Transaction*," beginning on page 99 of this proxy statement.

Background of the Otic Transaction

On July 25, 2016, the independent Data Monitoring Committee ("**DMC**") for Tokai's pivotal Phase 3 ARMOR3-SV trial of its lead product candidate, galeterone, met to review safety and efficacy data from the trial. Following the conclusion of the DMC meeting, the chairman of the DMC called Karen Ferrante, MD, Tokai's chief medical officer, to inform her that, based on a review of all available safety and efficacy data, the DMC had determined that the ARMOR3-SV trial would likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival for galeterone versus enzalutamide in men with AR-V7 positive mCRPC and recommended that enrollment in the trial be discontinued. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial.

Later on July 25, 2016, the Tokai board of directors (the "**Board**") held a telephonic meeting at which Dr. Ferrante reviewed the meeting of the DMC and the recommendations of the DMC with respect to the ARMOR3-SV trial. After a lengthy discussion, the Board agreed that Tokai should accept the DMC's recommendation and discontinue the trial. Jodie P. Morrison, president and chief executive officer, then reviewed plans for public disclosure of the trial discontinuation and for further analysis of the data from the trial. Ms. Morrison also discussed Tokai's current cash resources. The Board agreed to meet again on July 28, 2016 to discuss possible cost-cutting measures.

On July 26, 2016, prior to the opening of trading, Tokai issued a press release announcing the recommendation of the DMC and Tokai's plan to discontinue the ARMOR3-SV trial. Tokai's common stock closed at \$1.10 per share on July 26, 2016 as compared to a closing price of \$5.20 per share on July 25, 2016.

On July 28, 2016, the Board held a telephonic meeting at which it reviewed development options for galeterone and Tokai's preclinical ARDA program, Tokai's cash resources and actions that could be taken to

[Table of Contents](#)

conserve Tokai's cash resources while Tokai conducted its review of the galeterone and ARDA programs. After a discussion, the Board approved a plan to reduce the size of Tokai's workforce by approximately 60% to a total of ten full-time equivalent employees and the departure of certain members of Tokai's management. The Board also reviewed a range of possible strategic alternatives, including continuing the development of galeterone and/or the ARDA program, licensing or otherwise monetizing galeterone and/or the ARDA program, engaging in a reverse merger transaction or winding up operations and distributing existing net cash to Tokai's stockholders in a liquidation. The Board also directed management to initiate discussions with potential financial advisory firms in order to identify a firm to engage to assist the Board in evaluating Tokai's strategic alternatives.

Between July 28, 2016 and August 16, 2016, Tokai's management continued its analysis of the development programs for galeterone and the ARDA program and engaged in discussions with several financial advisory firms, including Wedbush, regarding assisting the Board with its evaluation of strategic alternatives. During this period, Tokai management routinely updated the Board through informal telephonic status update calls and email correspondence.

On August 16, 2016, the Board held a telephonic meeting at which Tokai management provided an update on its review of the data from the ARMOR3-SV trial and of the galeterone and ARDA development programs and recommended that Tokai discontinue enrollment in its ongoing Phase 2 ARMOR2 clinical trial of galeterone. At the meeting, Tokai management also reviewed Tokai's current cash resources and the impact of the reduction in force and trial discontinuations on Tokai's cash burn forecast, described the discussions that it had had with financial advisory firms and recommended that the Board engage Wedbush as Tokai's financial advisor. Following a discussion of these matters, the Board directed Tokai management to negotiate an engagement letter with Wedbush and to discontinue enrollment in the ongoing Phase 2 ARMOR2 trial. The Board also discussed the establishment of a committee of independent directors to oversee and guide a strategic transaction process and potential conflicts that certain directors could have if companies affiliated with them were participants in the strategic transaction process.

On August 30, 2016, the Board, acting by written action, authorized the Tokai management to enter into an engagement letter with Wedbush, and on August 31, 2016, Tokai formally engaged Wedbush to advise on strategic alternatives for Tokai to maximize stockholder value.

On September 6, 2016, the Board held a telephonic meeting in which representatives of Wedbush and Wilmer Cutler Pickering Hale and Dorr LLP, counsel to Tokai ("*WilmerHale*"), participated. At the meeting, representatives of Wedbush reviewed a recommended process for exploring strategic alternatives and a proposed timeline for a possible transaction. As part of this review, the representatives of Wedbush proposed criteria to be used to screen potential counterparties, including biopharmaceutical companies with product candidates in clinical trials or expected to be in clinical trials in 2017 and late-stage medical device companies, the valuations of which would warrant Tokai pre-combination stockholders continuing to own a double-digit percentage of the surviving company. Ms. Morrison then described a press release that Tokai proposed to issue announcing that the Board had formally initiated a review of strategic alternatives for Tokai focused on maximizing stockholder value and announcing that Tokai had engaged Wedbush as its financial advisor as part of its strategic review. After a discussion, the Board authorized the initiation of the strategic review and directed management to issue the press release as described.

At the September 6, 2016 meeting of the Board, the Board also established an independent transaction committee of the Board consisting of Cheryl Cohen and Stephen Buckley, as independent directors as defined in the NASDAQ Listing Rules, to oversee and guide the strategic transaction process (the "*Transaction Committee*"). The members of the Transaction Committee were selected by the Board based primarily on the members' knowledge of, and experience with, strategic transactions, experience in evaluating the prospects and relative value of potential strategic partners, operational and executive experience relative to the required diligence of the potential strategic partners, diversity of professional experience and ability to meet the time commitments of service on such committee. The Board delegated to the Transaction Committee the primary

[Table of Contents](#)

authority to review and evaluate proposals for strategic transactions, to review and evaluate the prospects for the strategic partners, to interface with Wedbush and to act on behalf of the Board in facilitating the review, analysis, evaluation, monitoring and exercise of general oversight of all proceedings and activities related to any strategic transaction proposal. The Transaction Committee was not delegated the authority to approve any particular transaction but was directed to provide recommendations to the Board with regards to the various proposals and/or strategic partners.

Following the conclusion of the September 6, 2016 Board meeting, the Transaction Committee held a telephonic meeting with representatives of Wedbush and WilmerHale. At the meeting, the representatives of Wedbush led a discussion regarding the process by which Tokai would explore potential strategic transactions, the criteria for screening potential counterparties and the process for conducting diligence on potential counterparties. After a discussion, the Transaction Committee directed Tokai management and Wedbush to commence the agreed upon process.

On September 8, 2016, upon confirmation that no companies affiliated with Apple Tree Partners would participate in the strategic transaction process, the Board appointed Seth Harrison, the Managing Director of Apple Tree Partners, to, and as chairman of, the Transaction Committee.

On September 8, 2016, Tokai issued a press release announcing that its Board had initiated a review of strategic alternatives for the company focused on maximizing stockholder value, that it had engaged Wedbush to act as its financial advisor and that Tokai anticipated that all patients enrolled in the ARMOR3-SV trial would discontinue treatment by the end of the year.

As described in greater detail below, between September 1, 2016 and December 21, 2016, members of Tokai management and representatives of Wedbush, acting at the direction and under the supervision of the Transaction Committee, conducted a process of identifying and evaluating potential strategic transactions with pharmaceutical and biotechnology companies. Working with Wedbush, Tokai identified and screened approximately 145 companies, held meetings or calls with the management of 40 companies, received written non-binding indications of interest from 24 companies, provided draft merger agreements to ten companies, received revised drafts of the draft merger agreement from four companies and entered into negotiations of the draft merger agreement with Otic, Company A and Company B. During the process, substantially all of the parties with which Tokai had discussions only expressed an interest in pursuing a reverse merger transaction, and none of these parties expressed an interest in acquiring galeterone or the ARDA program. As a result, the Transaction Committee primarily focused on a reverse merger transaction.

In evaluating potential parties for a transaction and narrowing the list of potential parties throughout the process, Tokai utilized a broad set of criteria that focused on a range of attributes and characteristics of such parties. This set of criteria was initially discussed by Tokai's Board in connection with its engagement of Wedbush and was refined by the Transaction Committee during the course of the process. In evaluating potential counterparties, the Transaction Committee considered (i) the depth of the counterparty's product pipeline and stage of development, (ii) risks relating to the clinical success of the counterparty's product candidates and operational risks, (iii) the market opportunity for the counterparty's product candidates if approved, (iv) the anticipated scope and timing of development and commercialization milestones, (v) the counterparty's management team, (vi) the counterparty's cash resources and the sufficiency of the expected financial resources of a combined company with the counterparty to achieve potentially meaningful milestones, either through resources to be obtained through financing activities consummated prior to the effectiveness of a transaction with Tokai or through the resources that would result from a transaction with Tokai, (vii) the counterparty's interest in Tokai's existing assets, management team, facilities and business, (viii) the expected board composition following a transaction, (ix) the availability of audited financial statements or the capability to produce such audited financial statements in order to satisfy applicable Exchange Act and/or Securities Act requirements, (x) valuation estimate and prospects for the counterparty and (xi) the counterparty's ability to expeditiously consummate a transaction with Tokai and risks related thereto. Tokai also requested information from each potential strategic partner as to its interest in continuing the development of galeterone or the ARDA program.

[Table of Contents](#)

In evaluating the proposed terms of potential transactions with counterparties and narrowing the list of potential counterparties throughout such process, the Transaction Committee also analyzed (i) the proposed valuation of the counterparty, (ii) the valuation of Tokai ascribed by such counterparty, (iii) the anticipated relative ownership of the combined entity immediately following the consummation of a transaction by Tokai's pre-combination stockholders and the stockholders of such counterparty and (iv) the counterparty's ability to consummate a transaction.

On September 1, 2016, representatives of Wedbush began contacting companies to gauge interest in a strategic transaction with Tokai. One of the companies contacted on September 1, 2016 was Otic. Based on an initial expression of interest by Greg Flesher, the chief executive officer of Otic, Wedbush sent Otic a confidentiality agreement on September 6, 2016. Tokai and Otic executed the confidentiality agreement on September 15, 2016.

On September 6, 2016, a member of the board of directors of Company A contacted Wedbush and expressed interest in exploring a possible strategic transaction with Tokai. Company A is a clinical stage company focused on respiratory disorders. Later that day, representatives of Wedbush spoke with the chief executive officer of Company A and, following that call, sent Company A a confidentiality agreement. The parties executed the confidentiality agreement on September 12, 2016. On September 12, 2016, representatives of Wedbush spoke further with the chief executive officer of Company A regarding the timing of a possible transaction, issues related to Tokai's ongoing shareholder litigation and Tokai's projected cash balance at the anticipated time of the closing of a transaction.

On September 21, 2016, the Board held a telephonic meeting in which representatives of Wedbush and WilmerHale participated. At the meeting, the representatives of Wedbush reviewed the process that had been adopted by the Transaction Committee and updated the Board on the number of counterparties that had been contacted and that had signed confidentiality agreements and, after a discussion, left the meeting. The Tokai management then updated the Board on Tokai's projected uses of cash and cash burn forecast, the status of the ARMOR2 and ARMOR3-SV clinical trials, and the exploration of strategic alternatives to maximize the value of galeterone. The Board then discussed and authorized Tokai management to enter into a consulting agreement with Apple Tree Life Sciences, Inc., an affiliate of Apple Tree Partners, under which Apple Tree agreed to provide consulting, advisory and related services to and for Tokai from time to time, including assisting Tokai in connection with its review of strategic alternatives and conducting diligence of potential counterparties. Under the agreement, there is no fee for Apple Tree's services except for reimbursement of out of pocket expenses.

On September 22, 2016, Tokai management participated in conference calls with the management teams of Otic and Company A. During each of these calls, the parties discussed a potential strategic transaction and the management of the potential counterparties presented a summary of their plans and activities.

On September 23, 2016, representatives of Wedbush contacted Company B, a clinical stage company focused on dermatologic disorders, to explore the possibility of a potential strategic transaction between Tokai and Company B. In response to a positive indication of interest, representatives of Wedbush sent Company B a confidentiality agreement and requested to schedule an initial meeting between the management teams of Tokai and Company B. The parties executed the confidentiality agreement on September 26, 2016.

On September 27, 2016, the Transaction Committee held a telephonic meeting in which representatives of Wedbush and WilmerHale participated. At the meeting, representatives of Wedbush updated the Transaction Committee on the strategic transaction process, including the 18 companies that had completed management presentations prior to the meeting. The Transaction Committee then discussed the draft process letter that had been circulated to the Transaction Committee encouraging potential counterparties to provide a written non-binding indication of interest with respect to a possible strategic transaction involving Tokai and directed Wedbush to deliver the process letter to each of the companies that had completed management presentations as of such date. Representatives of Wedbush noted that it had received an unsolicited indication of interest for a

[Table of Contents](#)

business combination transaction involving Tokai from one of the companies that had completed a management presentation, and the Transaction Committee agreed that the Transaction Committee would include the bidder in the strategic transaction process and consider the bidder's indication of interest with the other indications of interest received by Tokai. The Transaction Committee also agreed that as additional companies completed management presentations it would consider authorizing the delivery of process letters by email.

From the September 27, 2016 meeting until December 21, 2016, Wedbush sent process letters to 32 companies, including 30 companies prior to October 13, 2016 including Otic, Company A and Company B. Wedbush sent process letters to Otic and Company A on September 28, 2016.

On September 30, 2016, Tokai management participated in a conference call with the management team of Company B. During the call, the parties discussed a potential strategic transaction and the management team of Company B presented a summary of its plans and activities. Later that day, with the approval of the Transaction Committee, Wedbush sent a process letter to Company B.

On October 3, 2016, the management teams of Tokai and Company A met at Tokai's offices in Boston, Massachusetts, with representatives of Wedbush and Apple Tree Partners participating telephonically. During the meeting, Company A's management shared additional details regarding its plans and activities and responded to questions from Tokai management and its advisors.

Between October 6, 2016 and October 13, 2016, representatives of Wedbush received written non-binding indications of interest from 22 parties, including Otic, Company A and Company B, each detailing proposed terms for a strategic transaction between the parties and Tokai.

On October 10, 2016, Otic delivered to representatives of Wedbush its written non-binding indication of interest. In the indication of interest, Otic proposed a stock-for-stock transaction with current Otic shareholders receiving shares of Tokai common stock representing approximately 60% of the combined company and Tokai stockholders retaining ownership of approximately 40% of the Tokai common stock based on an ascribed value of \$33 million for Tokai and an assumed minimum amount of cash at closing. The indication of interest also noted the key areas of diligence to be performed, that Tokai would retain three of the planned seven board seats, the status of Otic's financial statements, that Otic's shareholders had indicated a willingness to invest in the combined company and that Otic's shareholders would agree to a 180-day lock up.

On October 13, 2016, the Transaction Committee held a meeting at the offices of Apple Tree Partners in New York, New York in which representatives of Wedbush, Apple Tree Partners and WilmerHale participated. At the meeting, representatives of Wedbush provided the Transaction Committee with an update regarding the strategic transaction process and the written non-binding indications of interests that Wedbush had received. Representatives of Wedbush reviewed for the Transaction Committee the key terms of each written indication of interest, including the ascribed valuation of each such party, the valuation ascribed to Tokai by each such party including the cash resources assumed to be held by Tokai upon the closing of a transaction, the anticipated ownership of the combined entity by Tokai's existing stockholders following the closing of a transaction, the cash resources that the combined entity was expected to have following a transaction, including the need for a concurrent financing, if any, and the number of members of the board of directors of the combined entity that Tokai would be entitled to designate. The Transaction Committee also considered and discussed the businesses of each such party using the criteria previously identified by the Tokai Board and the Transaction Committee (and previously summarized above), with the assistance and advice of representatives of Wedbush, Apple Tree Partners and Tokai management, including, among other things, the parties' products, the status and progress of clinical trials, the anticipated scope and timing of the commercialization of such parties' products, market opportunity and the experience of the management team of such party.

On this basis, the Transaction Committee categorized the potential counterparties into categories labeled high priority, medium priority and low priority, and directed Tokai's management and representatives to prioritize resources on exploring a potential strategic transaction with five of the high priority potential counterparties, including Company A and Company B, by circulating an initial draft of a merger agreement to

[Table of Contents](#)

such parties and organizing in-person diligence sessions which members of the Transaction Committee could attend, while continuing to review potential strategic transactions with other parties. The Transaction Committee directed Tokai management to conduct additional diligence regarding the financial resources of Otic and the willingness of Otic to conduct a concurrent financing before proceeding with Otic.

On October 14, 2016, representatives of Wedbush contacted Company B to schedule an in-person diligence session. In anticipation of this meeting, Wedbush requested access for Tokai and its advisors to Company B's virtual data room, which was provided on October 17, 2016.

On October 19, 2016, Wedbush delivered to Company B the initial draft of the merger agreement. The initial draft contemplated a reverse triangular merger of the counterparty and a wholly owned subsidiary of Tokai pursuant to which the stockholders of the counterparty would receive a number of shares of Tokai common stock based on a fixed exchange ratio (the amount of which was left undefined in the initial draft).

On October 20, 2016, Wedbush sent to Otic a list of diligence questions prepared by Tokai management and its advisors relating to intellectual property and business development matters. Otic reverted with a series of responses to the diligence questions on October 21, 2016.

On October 21, 2016, Tokai management held a due diligence call with advisors to Company B regarding Tokai's cash burn forecast.

On October 22, 2016, a representative of Brock Capital, the financial advisor for Company C, emailed Ms. Morrison to express Company C's interest in exploring a possible business combination between Company C and Tokai. Company C is a clinical stage company focused on developing cancer therapeutics. On October 31, 2016, Wedbush sent Company C a copy of the confidentiality agreement. The parties executed the confidentiality agreement on November 8, 2016.

Between October 26, 2016 and November 2, 2016, Tokai management and its advisors and members of the Transaction Committee held in-person diligence meetings with eight companies, including Otic and Company B. In connection with these meetings, Wedbush delivered the initial draft of the merger agreement to the eight companies.

On October 31, 2016, representatives of Wedbush contacted Otic to schedule an in-person diligence session. In anticipation of the diligence session, Wedbush requested access for Tokai and its advisors to Otic's virtual data room, which was provided on October 31, 2016. Otic continued to add requested diligence items to its virtual data room from October 31, 2016 to December 21, 2016. The in-person diligence session with Otic was held on November 2, 2016.

On November 4, 2016, a representative of Company C informed Wedbush that the audit of Company C's financial statements for 2014 and 2015 had not yet been completed and that the audited financial statement would not be available until February 2017.

On November 7, 2016, the Transaction Committee held a telephonic meeting in which representatives of Wedbush, Apple Tree Partners and WilmerHale participated. At the meeting, the Transaction Committee reviewed the in-person diligence meetings that Tokai management and the Transaction Committee had held with potential counterparties, and directed Tokai management and Wedbush to prioritize discussions with three of the counterparties: Otic, Company A and Company B.

On November 9, 2016, Otic delivered to Wedbush a list of diligence questions and requested diligence calls with Tokai management and the appropriate representatives of Tokai.

On November 10, 2016, Tokai management participated in a conference call with the management team of Company C. During the call, the parties discussed a potential strategic transaction, and the management team of Company C presented a summary of its plans and activities.

[Table of Contents](#)

On November 11, 2016, representatives of Otic and Tokai conducted diligence calls regarding general and administrative matters and the galeterone and ARDA programs.

On November 14, 2016, representatives of Otic and Tokai and their legal counsel conducted a diligence call regarding Tokai's outstanding litigation.

In addition, on November 14, 2016, Otic delivered to Wedbush a revised draft of the merger agreement, which Wedbush then delivered to Tokai management and to representatives of WilmerHale. The revised draft of the merger agreement received from Otic indicated Otic's preference to structure the transaction as a share purchase pursuant to which Tokai would acquire Otic's outstanding shares of capital stock directly from Otic shareholders rather than through a merger transaction in exchange for a number of shares of Tokai common stock to be issued to Otic shareholders equal to the number of shares necessary to cause the pre-combination stockholders of Tokai to own a specified percentage of the combined entity on a fully-diluted basis and the pre-combination equityholders of Otic to own a specified percentage of the combined entity on a fully-diluted basis. Other notable terms in the draft included (i) the elimination of all negative operating covenants that would apply to Otic between signing of the share purchase agreement and the closing of the transaction, (ii) the imposition of a strict limit on the pre-closing expenditures of Tokai, (iii) the requirement that Tokai seek stockholder approval for a reverse stock split if required for Tokai to maintain its listing on The NASDAQ Global Market and (iv) a termination fee, payable by Tokai, in the event, among other events, that Tokai terminated the share purchase agreement following any material breach of Tokai's representations, warranties or covenants in the share purchase agreement.

On November 17, 2016, with the approval of the Transaction Committee, Wedbush sent a process letter to Company C.

On November 18, 2016, Company C provided representatives of Tokai and its advisors with access to its virtual data room. Company C continued to add requested diligence items to its virtual data room from November 18, 2016 to December 7, 2016.

Between November 18, 2016 and November 21, 2016, Tokai management and Tokai's advisors held due diligence calls with Company B management and its advisors regarding legal, human resource and tax matters.

Between November 21, 2016 and November 23, 2016, Wedbush and representatives of Company C had multiple communications regarding the strategic transaction process, the desired timing of the close of a transaction and the status of the audit of Company C's financial statements.

Between November 21, 2016 and December 12, 2016, Tokai management and its advisors had multiple meetings and other communications with Otic regarding Otic's product development plans and intellectual property matters and conducted diligence regarding the market potential of OP-02, Otic's lead product.

On November 22, 2016, representatives of Wilmer Hale held a conference call with representatives of Gibson Dunn & Crutcher LLP, counsel to Otic ("**Gibson Dunn**"), to discuss the proposed revisions to the structure of the transaction referenced in Otic's draft share purchase agreement and to discuss other terms in the share purchase agreement, including the limitations on expenditures of Tokai, the inclusion of negative operating covenants applicable to Otic and the circumstances under which Tokai would owe a termination fee to Otic.

In addition, on November 22, 2016, Company B delivered to representatives of Wedbush a revised draft of the merger agreement, which Wedbush then delivered to Tokai management and to representatives of WilmerHale. The revised merger agreement did not specify the proposed exchange ratio but provided for an adjustment to the exchange ratio based on Tokai's net cash at closing and for a reciprocal and equal termination fee.

[Table of Contents](#)

On November 23, 2016, the management teams of Tokai and Company C held a diligence call regarding financial and research and development matters and the logistics and timing of a possible transaction.

On November 28, 2016, Company C submitted a written non-binding indication of interest.

On November 29, 2016, representatives of Tokai and Otic held an in-person meeting at the offices of Apple Tree Partners in New York. The attendees included Ms. Morrison, Dr. Harrison, Mr. Flesher and Keith Katkin, the chairman of the board of directors of Otic. At the meeting, the parties discussed the terms of Otic's offer, the potential composition of the board of directors following the closing of a transaction, requirements for a concurrent financing and potential investors with which Otic had already held meetings and which might have interest in participating in a concurrent financing. The representatives of Otic also provided the Tokai representatives with additional information regarding Otic's development plans for its lead product candidates, OP-01 and OP-02. After a discussion, the Otic representatives proposed that the companies enter into a period of exclusive negotiation, which was rejected by Tokai upon authorization of the Transaction Committee.

On November 29, 2016, a member of the board of directors of Company A contacted a representative of Wedbush to advise the Wedbush representative that there had been a change in the management of the Company A and that the Company A board of directors was reconsidering the terms of the non-binding indication of interest that it had provided to Tokai on October 10, 2016.

In addition, on November 29, 2016, representatives of WilmerHale held a call with Morrison Foerster, counsel to Company B, to discuss the revised draft of the merger agreement that had been provided by Company B.

On December 1, 2016, the management of Tokai held an update call with members of Company A's board of directors and management during which Company A informed Tokai management of the change in its management and provided additional information about its clinical development program and its partnering efforts for its lead product. After a discussion, the parties agreed to hold an in-person diligence meeting, which meeting occurred on December 5, 2016 at Tokai's offices in Boston, Massachusetts. Representatives of Wedbush and Apple Tree Partners participated in the meeting telephonically.

On December 1, 2016, the Transaction Committee held a telephonic meeting in which representatives of Wedbush and WilmerHale participated. At the meeting, the representatives of Wedbush described the status of discussions with Otic, Company B and Company C and noted that diligence with three other companies, including Company A, was ongoing. The Transaction Committee then discussed the potential transaction with Company A. Representatives of WilmerHale then advised the Transaction Committee on the status of the negotiations of the share purchase agreement with Otic and the merger agreement with Company B, noting that approaches to resolving the principal legal issues in the agreements had largely been agreed upon, and that both parties had agreed that they would accept a covenant from Tokai that its pre-closing expenditures would be consistent with the financial model that Tokai had provided to both parties as part of their diligence with a basket to address overages on planned expenditures and with permitted deviations from the model for matters outside Tokai's control. The representatives of WilmerHale also outlined the differences in timing of a transaction with Otic due to the ability to not have to file a registration statement on Form S-4. After a discussion, the committee directed WilmerHale to revise the agreement with Otic and deliver it to Otic and Gibson Dunn, but not to revise the Company B draft until further diligence of Company B was conducted and until Company B had improved its valuation terms and the proposed ownership percentage of the pre-combination Tokai stockholders following the closing of the transaction. The Transaction Committee also directed Tokai management team and the Wedbush representatives to continue the diligence and discussions with Company A and to provide Company A a draft of the merger agreement. On December 1, 2016, Wedbush delivered to Company A the draft merger agreement.

On December 1, 2016, a representative of WilmerHale delivered to representatives of Otic and Gibson Dunn a revised share purchase agreement.

In addition, on December 5, 2016, a representative of WilmerHale delivered to Morrison Foerster a revised draft of the merger agreement.

[Table of Contents](#)

On December 5, 2016, representatives of Company C informed representatives of Wedbush that Company C had selected a new auditing firm and that Company C expected that its audited financial statements could be available in early January 2017.

On December 6, 2016, the Transaction Committee held a telephonic meeting in which representatives of Wedbush and WilmerHale participated. At the meeting, the Transaction Committee discussed the non-binding indication of interest that Tokai had been advised that it would receive from Company A, the findings of the additional diligence that Tokai and its representatives had conducted on the business of Company A and the possible timing of a transaction with Company A given the level of diligence conducted and that Tokai had not yet received the revised indication of interest or a draft of the merger agreement from Company A. The Transaction Committee also discussed the status of discussions with Otic, the financing plan that Otic had proposed and the Otic business opportunity and the remaining diligence to be conducted. Following a discussion of the status of Tokai's interactions with Company B, Company C and other potential counterparties, the Transaction Committee directed Tokai management and the Wedbush representatives to prioritize efforts towards the execution of a transaction with Otic while continuing to conduct diligence regarding Company A and Company C. The Transaction Committee also directed the Wedbush representatives to advise Company B that it needed to improve its valuation terms and the proposed ownership percentage of the pre-combination Tokai stockholders following the closing of the transaction in order to remain in the process.

On December 6, 2016, a representative of Morrison Foerster delivered to WilmerHale a revised draft of the merger agreement. In connection with the delivery of the revised merger agreement, Morrison Foerster advised WilmerHale that Company B considered the revised draft to be final.

On December 7, 2016, Gibson Dunn delivered a revised Otic share purchase agreement to representatives of WilmerHale.

On December 7, 2016, Company A submitted a revised written non-binding indication of interest that was consistent with the proposal that had been described at the meeting of the Transaction Committee and that provided for, among other things, Ms. Morrison to be retained as President and Chief Executive Officer of the combined company.

On December 9, 2016, representatives of Company C submitted a revised written non-binding indication of interest on behalf of Company C that outlined Company C's proposal for a concurrent financing and the ownership split among Company C and Tokai's pre-combination stockholders following the closing of a transaction and the concurrent financing, provided for an adjustment to the exchange ratio in the event that Tokai's cash position at closing was less than agreed upon and set forth a number of matters that were to be the subject of Company C's diligence.

From December 10, 2016 through December 21, 2016, the management teams of Tokai and Otic engaged in numerous discussions regarding the timing of the execution and delivery of a share purchase agreement and the documentation and timing for a concurrent financing.

On December 11, 2016, WilmerHale delivered a revised Otic share purchase agreement to Gibson Dunn.

On December 13, 2016, representatives of WilmerHale held a call with representatives of Cooley LLP, counsel to Company A, regarding the transaction structure and the terms of the support agreements to be entered into in connection with the merger agreement.

On December 14, 2016, Gibson Dunn delivered a revised Otic share purchase agreement to WilmerHale.

On December 14, 2016, the Board held a meeting at the offices of Tokai in Boston, Massachusetts in which representatives of Wedbush and WilmerHale participated. At the meeting, the Tokai management

[Table of Contents](#)

provided the Board with an update on Tokai's outstanding litigation, the ARMOR2 and ARMOR3-SV clinical trials, management's analysis of the galeterone and ARDA development programs and possible next steps in those programs and Tokai's cash resources and cash burn forecast. Ms. Morrison and the representatives of Wedbush then reviewed the status of discussions with the potential counterparties on the Transaction Committee's high priority list, including Otic, Company A and Company C, and noted that Company B had not agreed to improve its valuation terms and was no longer part of the strategic transaction process. The Board then discussed with Tokai management and the Wedbush representatives concerns regarding the business prospects of Company A and regarding the uncertainties of a transaction with Company C given the diligence still to be conducted, the fact that Company C had not yet provided its comments on the merger agreement and the timing of Company C's financial statements. The Board then discussed with Tokai management and the Wedbush representatives the additional diligence that had been conducted regarding Otic's business, the additional financing that Otic would be able to raise and the anticipated timing of a transaction with Otic. The representatives of WilmerHale then reviewed with the Board its fiduciary duties in connection with considering and approving a transaction with Otic and summarized the terms of the proposed share purchase agreement and the related agreements. Next, the representatives of Wedbush reviewed the strategic transaction process that had been conducted since September 1, 2016 and its preliminary analysis of the financial terms of the proposed transaction with Otic. Representatives of WilmerHale and Wedbush also responded to a number of questions from the Board regarding the fiduciary duties of directors, the terms of the proposed transaction, the terms of the share purchase agreement and the related agreements, the strategic process, the methodologies used by Wedbush in preparing its financial analysis and next steps.

On December 15, 2016, the management teams of Tokai and Otic held a telephonic meeting to discuss the calculation of the exchange ratio and the timing of execution of definitive agreements for a concurrent financing.

On December 15, 2016, representatives of Company A delivered to the Tokai management team a revised draft of the merger agreement.

On December 21, 2016, the Board held a telephonic meeting in which representatives of Wedbush and WilmerHale participated. Representatives of WilmerHale reviewed the final form of the share purchase agreement to be entered into with Otic and the related agreements, including the agreements relating to the financing of the combined company following the closing of the transaction. Representatives of Wedbush reviewed with the Board its analysis of the financial terms of the proposed transaction and delivered to the Board its oral opinion to the effect that, as of December 21, 2016, and based upon and subject to various considerations and assumptions set forth in its written opinion, the exchange ratio was fair to the holders of Tokai common stock from a financial point of view. The Wedbush representatives subsequently confirmed Wedbush's oral opinion by delivering its written opinion, dated December 21, 2016, to the Board. The written opinion of Wedbush is attached hereto as *Annex D*. Representatives of WilmerHale and Wedbush then responded to a number of questions from the Board regarding the fiduciary duties of directors, the terms of the proposed transaction, the terms of the share purchase agreement and the related agreements, the strategic process, Wedbush's financial analysis and next steps. Following these discussions, and review and discussion among the members of the Board, including the relative merits of executing the share purchase agreement versus remaining a standalone company, the Board, among other actions, unanimously (a) determined that the Otic Transaction, the Share Purchase Agreement, the issuances of shares of Tokai common stock pursuant to the Share Purchase Agreement and the Tokai Stock Purchase Agreement and the other transactions contemplated by the Share Purchase Agreement, are fair to, advisable and in the best interest of Tokai and its stockholders, (b) approved the Otic Transaction, the Share Purchase Agreement, the Tokai Stock Purchase Agreement, the issuance of shares of Tokai common stock pursuant to the Share Purchase Agreement and the Tokai Stock Purchase Agreement and the other transactions contemplated by the Share Purchase Agreement, (c) authorized Tokai to enter into and perform its obligations under the Share Purchase Agreement and (d) resolved to recommend that the Tokai stockholders vote to approve the issuances of shares of Tokai common stock pursuant to the terms of the Share Purchase Agreement and the Tokai Stock Purchase Agreement.

[Table of Contents](#)

Following the adjournment of the meeting of the Board on December 21, 2016, Tokai, Otic and the Otic shareholders executed and delivered the share purchase agreement and the related agreements. The signing of the share purchase agreement was publicly announced on December 22, 2016 prior to the opening of trading of the Tokai common stock on The NASDAQ Global Market.

Recommendation of the Tokai Board of Directors

The Tokai board of directors has determined and believes that each of the Share Issuances Proposal, the Reverse Stock Split Proposal and the Adjournment Proposal is fair to, advisable, and in the best interests of Tokai and its stockholders and has approved such items. The Tokai board of directors recommends that Tokai stockholders vote “FOR” each of the Share Issuances Proposal, the Reverse Stock Split Proposal and the Adjournment Proposal. For more information on the Tokai board of directors’ recommendations see the section entitled “*Information About the Special Meeting—Recommendation of the Tokai Board of Directors*,” beginning on page 65 of this proxy statement and the section entitled “*Terms of the Share Purchase Agreement—Changes to Board Recommendation*,” beginning on page 103 of this proxy statement.

Reasons for the Otic Transaction

The Tokai board of directors and executive management team have regularly reviewed and discussed Tokai’s operating and strategic plans, both near-term and long-term, as well as potential partnerships and strategic transactions, in an effort to enhance stockholder value. These reviews and discussions have focused, among other things, on the opportunities and risks associated with Tokai’s business and financial condition and strategic relationships and other strategic options. In September 2016, Tokai announced that its board of directors had initiated a review of strategic alternatives for the company focused on maximizing stockholder value. Potential strategic alternatives that were explored or evaluated as part of this review included a sale of Tokai, a reverse merger, a business combination or a sale, license or other disposition of corporate assets of Tokai. In conjunction with this process, Tokai continued to assess the best path forward for its galeterone clinical trial program.

In the course of its evaluation of the Otic Transaction and the Share Purchase Agreement, the Tokai board of directors held numerous meetings, consulted with Tokai’s senior management, legal counsel, financial advisor, and certain significant stockholders, and reviewed and assessed a significant amount of information and, in reaching its unanimous decision to approve Share Purchase Agreement, the issuance of Tokai common stock pursuant to the Share Purchase Agreement and the other transactions contemplated by the Share Purchase Agreement, the Tokai board of directors considered a number of factors, including, among others, the following:

- The Tokai board of directors’ belief, based in part on the judgment, advice and analysis of Tokai management with respect to the potential strategic, financial and operational benefits of the Otic Transaction (which judgment, advice and analysis was informed in part by the business, technical, financial, accounting and legal due diligence investigation performed by Tokai and its advisors on Otic), that Otic’s portfolio of products for ENT disorders may provide new medical benefits for patients and returns for investors.
- The Tokai board of directors’ view, following a review with Tokai’s management of Otic’s current plans for developing its product portfolio, of the likelihood that the combined company would possess sufficient financial resources to allow the management team to focus on the continued development and anticipated commercialization of Otic’s product candidates for ENT disorders. The Tokai board of directors’ analysis included the new capital to be invested prior to or upon the closing of the Otic Transaction through the Equity Financing. The Tokai board of directors also considered the possibility that the combined company would be able to take advantage of the potential benefits resulting from the combination of the Tokai public company structure with the Otic business to raise additional funds in the future, if necessary.

Table of Contents

- The Tokai board of directors' consideration of the valuation and business prospects of all the potential strategic transaction candidates. After considering the comprehensive diligence review that Tokai management had completed of ten other prospective transaction candidates, the board concluded that the transaction with Otic would create a publicly traded company focused on improving patient access to important medicines that could create more value for Tokai's stockholders than any of the other proposals that the board had received.
- The Tokai board of directors' conclusion that given the ownership position of the Tokai stockholders following the transaction, the Otic Transaction would provide existing Tokai stockholders a significant opportunity to participate in the potential growth of the combined company following the Otic Transaction.
- The Tokai board of directors' consideration of the strength of the balance sheet of the combined company resulting from Otic's current cash reserves, the new capital to be invested prior to or upon the closing of the Otic Transaction through the Equity Financing and the approximately \$20.0 million net cash that was expected to be retained by Tokai upon completion of the Otic Transaction.
- The Tokai board of directors' view that the combined company will be led by an experienced senior management team and a board of directors with representation from each of the current boards of directors of Tokai and Otic.
- The Tokai board of directors' consideration of the financial analyses of Wedbush, including its opinion to the board of directors as to the fairness to the Tokai stockholders, from a financial point of view and as of the date of the opinion, of the exchange ratio in connection with the Otic Transaction, as more fully described below under the caption "*The Otic Transaction—Opinion of Tokai's Financial Advisor,*" beginning on page 86 in this proxy statement.

The Tokai board of directors also reviewed the recent results of operations and financial condition of Tokai, including:

- Tokai's decision to discontinue its ARMOR3-SV pivotal Phase 3 clinical trial of galeterone, following the recommendation made by the trial's independent data monitoring committee;
- Tokai's decision to discontinue enrollment in its Phase 2 ARMOR2 expansion trial of galeterone;
- Tokai's workforce reduction announced in July 2016;
- the loss of the operational capabilities of Tokai, and the risks associated with continuing to operate Tokai on a stand-alone basis, including the need to rebuild infrastructure and management to continue its operations;
- the results of substantial efforts made over a significant period of time by Tokai's management and financial advisors to solicit strategic alternatives for Tokai to the transaction, including the discussions that Tokai management, Tokai's representatives and the Tokai board of directors had in 2016 with other potential strategic transaction candidates;
- current financial market conditions and historical market prices, volatility and trading information with respect to Tokai common stock; and
- the risks, costs and timing associated with a potential liquidation of Tokai.

The Tokai board of directors also reviewed the terms of the Share Purchase Agreement and associated transactions, including:

- the number of shares of Tokai common stock to be issued in the Otic Transaction;
- the number and nature of the conditions to Otic's obligation to consummate the Otic Transaction and the limited risk of non-satisfaction of such conditions as well as the likelihood that the Otic Transaction will be consummated on a timely basis;

Table of Contents

- the rights of, and limitations on, Tokai under the Share Purchase Agreement to consider certain unsolicited acquisition proposals under certain circumstances should Tokai receive a superior proposal;
- the reasonableness of the potential termination fee of \$1.0 million, which could become payable by Tokai if the Share Purchase Agreement is terminated in certain circumstances;
- the agreement by all of the Otic shareholders to enter into the Share Purchase Agreement and sell their Otic shares to Tokai in exchange for Tokai shares pursuant to the Share Purchase Agreement; and
- the belief that the terms of the Share Purchase Agreement, including the parties' representations, warranties and covenants, and the conditions to their respective obligations, are reasonable under the circumstances.

In the course of its deliberations, the Tokai board of directors also considered a variety of risks and other countervailing factors related to entering into the Otic Transaction, including:

- the potential effect of the \$1.0 million termination fee payable by Tokai upon the occurrence of certain events in deterring other potential acquirors from proposing an alternative transaction that may be more advantageous to Tokai stockholders;
- the substantial expenses to be incurred in connection with the transaction;
- the possible volatility, at least in the short term, of the trading price of the Tokai common stock resulting from the announcement of the transaction;
- the risk that the Otic Transaction might not be consummated in a timely manner or at all and the potential adverse effect of the public announcement of the Otic Transaction or on the delay or failure to complete the Otic Transaction on the reputation of Tokai;
- the risk to the business of Tokai, operations and financial results in the event that the Otic Transaction is not consummated;
- the strategic direction of the continuing entity following the completion of the transaction, which will be determined by Otic's management and a board of directors initially comprised of a majority of the members of the current Otic board of directors; and
- various other risks associated with the combined company and the transaction, including those described in the section entitled "*Cautionary Statement Regarding Forward-Looking Information*" in this proxy statement.

The foregoing information and factors considered by the Tokai board of directors are not intended to be exhaustive but are believed to include all of the material factors considered by the Tokai board of directors. In view of the wide variety of factors considered in connection with its evaluation of the Otic Transaction and the complexity of these matters, the Tokai board of directors did not find it useful, and did not attempt, to quantify, rank or otherwise assign relative weights to these factors. In considering the factors described above, individual members of the Tokai board of directors may have given different weight to different factors. The Tokai board of directors conducted an overall analysis of the factors described above, including thorough discussions with, and questioning of, the Tokai management team and the legal and financial advisors of Tokai, and considered the factors overall to be favorable to, and to support, its determination.

Interests of Tokai's Directors and Executive Officers

In considering the recommendation of the Tokai board of directors with respect to the related issuances of shares of Tokai common stock pursuant to the Share Purchase Agreement and the Tokai Stock Purchase Agreement and the other matters to be voted upon by Tokai stockholders at the Tokai special meeting, Tokai

[Table of Contents](#)

stockholders should be aware that certain members of the Tokai board of directors and executive officers of Tokai have interests in the Otic Transaction that may be different from, or in addition to, interests they have as Tokai stockholders generally. The members of the Tokai board of directors were aware of the different or additional interests and considered these interests, among other matters, in evaluating and negotiating the Share Purchase Agreement and the Otic Transaction, and in recommending to the stockholders that the Share Issuances Proposal be approved. See the sections entitled “*The Otic Transaction—Recommendation of the Tokai Board of Directors*” and “*The Otic Transaction—Reasons for the Otic Transaction*,” each beginning on page 81 of this proxy statement. The stockholders should take these interests into account in deciding whether to vote “FOR” the Share Issuances Proposal and the other matters to be voted upon by Tokai stockholders at the Tokai special meeting. These interests are described in more detail below, and certain of them are quantified in the narrative and the table below.

Indemnification of Directors and Officers

Tokai has entered into indemnification agreements with each of its directors and executive officers. These agreements, among other things, require Tokai to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permitted by Delaware law, against liabilities that may arise by reason of their service to Tokai or at Tokai’s direction, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. Further, pursuant to the Share Purchase Agreement, Tokai, Otic and the Sellers agreed that, from the closing of the Otic Transaction through the sixth anniversary of the closing, Tokai will indemnify and hold harmless each person who as of the date of the Share Purchase Agreement is, or who becomes prior to the closing, or has been at any time prior to the closing of the Otic Transaction, a director or officer of Tokai or Otic.

Tokai also maintains an insurance policy that insures its directors and officers against certain liabilities, including liabilities arising under applicable securities laws and Tokai has agreed to maintain in effect for six years after the closing of the Otic Transaction Tokai’s existing directors’ and officers’ insurance policies in place as of the date of the Share Purchase Agreement, or prior to the closing, to purchase a six-year “tail” policy under its own existing directors’ and officers’ liability insurance policy.

Vesting of Director Stock Options

Pursuant to the stock option agreements evidencing the stock options held by each of Tokai’s non-employee directors, upon a change in control of Tokai, such non-employee director’s stock options will vest in full. Tokai’s board of directors has determined that the Otic Transaction constitutes a change in control for purpose of Tokai’s stock awards.

Quantification of Payments and Benefits to Tokai’s Named Executive Officers

This section sets forth the information required by Item 402(t) of Regulation S-K regarding the compensation for each of Tokai’s named executive officers that is based on or otherwise relates to the Otic Transaction. This compensation is referred to as “golden parachute” compensation by the applicable SEC disclosure rules, and in this section Tokai uses such term to describe the transaction-related compensation payable to Tokai’s named executive officers.

Employment Agreement with Ms. Morrison

Tokai’s employment agreement with Ms. Morrison provides for certain benefits upon termination of her employment under specified conditions. Under the terms of the employment agreement with Ms. Morrison, if Ms. Morrison’s employment is terminated by Tokai without cause or by Ms. Morrison for good reason prior to a change in control, each as defined in her employment agreement, and subject to Ms. Morrison’s execution of a general release of potential claims against Tokai, Tokai has agreed to continue to pay Ms. Morrison her then-current base salary for a period of 12 months and to provide medical and dental benefits (to the extent that she was receiving them at the time she ceased to be employed by us) for a period of up to 12 months.

[Table of Contents](#)

In lieu of receiving the benefits described above in connection with a termination of employment, if Ms. Morrison's employment is terminated by Tokai without cause or by Ms. Morrison for good reason upon or within one year following a change in control, and subject to Ms. Morrison's execution of a general release of potential claims against Tokai, Tokai has agreed to continue to pay Ms. Morrison her then-current base salary for a period of 18 months and to provide medical and dental benefits (to the extent that she was receiving them at the time she ceased to be employed by Tokai) for a period of up to 18 months and to pay her an amount equal to her target bonus for the year in which the termination occurs.

In addition, with respect to each stock option that Tokai has granted Ms. Morrison that has not yet vested, Tokai has agreed that if Ms. Morrison is terminated without cause or resigns for good reason in connection with or within one year after a change in control of Tokai (as defined in the applicable stock option agreement), then that stock option will vest in full.

The Otic Transaction constitutes a change in control under the employment agreement and the stock option agreements entered into with Ms. Morrison.

Employment Agreement with Mr. McBride

Tokai's employment agreement with Mr. McBride provides for certain benefits upon termination of his employment under specified conditions. Under the terms of Mr. McBride's employment agreement, if Mr. McBride's employment is terminated by Tokai without cause, and subject to Mr. McBride's execution of a general release of potential claims against Tokai, Tokai has agreed to continue to pay Mr. McBride's then-current base salary for a period of six months and to provide medical and dental benefits (to the extent that he was receiving them at the time he ceased to be employed by us) for a period of up to six months.

In lieu of receiving the benefits described above in connection with a termination of employment, if Mr. McBride's employment is terminated by Tokai without cause or by Mr. McBride for good reason upon or within one year following a change in control, and subject to Mr. McBride's execution of a general release of potential claims against Tokai, Tokai has agreed to continue to pay Mr. McBride his then-current base salary for a period of 12 months and to provide medical and dental benefits (to the extent that he was receiving them at the time he ceased to be employed by Tokai) for a period of up to 12 months and to pay him an amount equal to his target bonus for the year in which the termination occurs.

In addition, under each stock option agreement that Tokai has entered into with Mr. McBride and has not yet vested, Tokai has agreed that if Mr. McBride is terminated without cause or resigns for good reason in connection with or within one year after a change in control of Tokai (as defined in the applicable stock option agreement), then that stock option will vest in full.

The Otic Transaction constitutes a change in control under the employment agreement and the stock option agreements entered into with Mr. McBride.

Quantification of Change in Control and Termination Payments and Benefits to Tokai's Named Executive Officers

In accordance with Item 402(t) of Regulation S-K, the table below sets forth the amount of payments and benefits that each of Tokai's named executive officers may receive in connection with the transaction, assuming that the Otic Transaction was consummated and such executive officer experienced a qualifying termination on January 20, 2017. Dr. Karen Ferrante, Tokai's former Chief Medical Officer, retired from Tokai effective August 31, 2016, and Gerald Quirk, Tokai's former Executive Vice President, Business Operations and General Counsel, ceased employment with Tokai effective August 31, 2016. Neither Dr. Ferrante nor Mr. Quirk will receive any additional compensation as a result of the Otic Transaction. The amounts below are determined using a per share price of the Tokai closing price of \$1.09, which represents the average closing market price of Tokai's securities over the first five business days following the first public announcement of the transaction. As

[Table of Contents](#)

a result of the foregoing assumptions, the actual amounts, if any, to be received by a named executive officer may materially differ from the amounts set forth below.

<u>Name</u>	<u>Cash (1)</u>	<u>Equity Awards (2)</u>	<u>Perquisites/ Benefits</u>	<u>Total</u>
Jodie Morrison	\$1,050,000	—	\$ 44,284(3)	\$1,094,284
John McBride	\$ 550,530	—	—	\$ 550,530

- (1) Amounts in this column represent the total cash severance payment to be paid to each executive upon a termination of employment without “cause” or a termination for “good reason” (as defined in each executive’s respective employment arrangement), subject to the execution and non-revocation of a general release of claims in favor of Tokai, including amounts equal to each executive’s target bonuses assuming the termination occurs in 2017.
- (2) All outstanding stock options for the named executive officers have exercise prices above \$1.09 and therefore are disregarded for this purpose.
- (3) Under Ms. Morrison’s executive agreement, upon a “double trigger” qualifying termination within the period of time commencing on the closing of the Otic Transaction and ending one year following the closing of the transaction, Ms. Morrison is entitled to continue to receive medical and dental benefits to the same extent provided by Tokai prior to such qualifying termination for up to 18 months.

Opinion of Tokai’s Financial Advisor

Scope of the Assignment

In August 2016, the Tokai board of directors engaged Wedbush to provide financial advisory and investment banking services in connection with evaluating and considering potential strategic transactions, and ultimately requested that Wedbush render an opinion as to whether the exchange ratio in connection with the transaction, as provided in the Share Purchase Agreement, was fair to the stockholders of Tokai from a financial point of view. At the December 21, 2016 meeting of the Tokai board of directors, Wedbush rendered its oral opinion, subsequently confirmed by delivery of a written opinion dated December 21, 2016, to the Tokai board of directors that, as of the date of such opinion, and based upon the assumptions made, procedures followed, matters considered, and qualifications and limitations of the review set forth in its written opinion, the exchange ratio in connection with the transaction was fair to the stockholders of Tokai from a financial point of view.

The full text of Wedbush’s written opinion, which sets forth the procedures followed, assumptions made, matters considered, and qualifications and limitations of the review undertaken in connection with such opinion, is attached to this proxy statement as *Annex B*. Wedbush’s opinion was intended for the use and benefit of the Tokai board of directors (in its capacity as such) in connection with its evaluation of the transaction. Wedbush’s opinion was not intended to be used for any other purpose without Wedbush’s prior written consent in each instance, except as Tokai’s counsel advises is required by law. Wedbush has consented to the use of Wedbush’s opinion in this proxy statement. Wedbush’s opinion did not address Tokai’s underlying business decision to enter into the Share Purchase Agreement or complete the transaction or the relative merits of the transaction compared to any alternative transactions or strategies that were or may be available to Tokai, or as to the likelihood of the consummation of the transaction, and did not constitute a recommendation to the Tokai board of directors as to how to act or to any Tokai stockholder or any other person as to how to vote with respect to the transaction or any other matter (including the amount of consideration to be paid). The following summary of Wedbush’s opinion is qualified in its entirety by reference to the full text of such opinion.

[Table of Contents](#)

For purposes of its opinion and in connection with its review of the exchange ratio in connection with the transaction, Wedbush, among other things:

- reviewed a draft of the Share Purchase Agreement dated December 21, 2016;
- reviewed certain publicly available business and financial information relating to Tokai and Otic, respectively;
- reviewed certain internal information, primarily financial in nature, including financial and operating data furnished to Wedbush by the managements of Tokai and Otic, respectively, and approved for Wedbush's use by Tokai;
- reviewed certain publicly available information with respect to other companies in the biopharmaceutical industry that Wedbush believed to be comparable in certain respects to Tokai and to Otic;
- considered the financial terms, to the extent publicly available, of selected recent business combinations and initial public offerings involving companies in the biopharmaceutical industry that Wedbush believed to be comparable in certain respects to Tokai and to Otic, in whole or in part, and to the transaction; and
- made inquiries regarding and discussed the Share Purchase Agreement and other matters related thereto with Tokai and its legal counsel.

In addition, Wedbush held discussions with the management of Tokai and Otic concerning their views as to the financial and other information described in the bullet points above. Wedbush also conducted such other analyses and examinations and considered such other financial, economic and market criteria as Wedbush deemed appropriate to arrive at its opinion.

In rendering its opinion, Wedbush relied upon and assumed, without independent verification, the accuracy and completeness of all information that was publicly available or was furnished to or discussed with Wedbush by Tokai, Otic or any other party to the Share Purchase Agreement or otherwise reviewed by Wedbush. With respect to information provided to or reviewed by it, Wedbush was advised by management of Tokai and Otic that such information was reasonably prepared on bases reflecting the best currently available estimates and judgments of management of Tokai or Otic, as applicable. Wedbush did not express any view as to the reasonableness of such financial information or the assumptions on which it was based.

Wedbush further relied on the assurances of Tokai's management that they were unaware of any facts that would make the information provided to Wedbush incomplete or misleading. Except for certain estimates of liabilities expected to be incurred by Tokai in connection with a potential liquidation of Tokai prepared by management of Tokai and estimated equity values of Tokai upon liquidation prepared by management of Tokai, Wedbush did not make and was not provided with any independent evaluations or appraisals of any of the assets, properties, liabilities (including any contingent, derivative or off-balance-sheet assets or liabilities) or securities, nor did Wedbush make any physical inspection of the properties or assets, of Tokai or Otic. Further, as the Tokai board of directors was aware, Otic's management did not provide Wedbush with, and Wedbush did not otherwise have access to, financial forecasts regarding Otic's business, other than certain expense forecasts for the five years ended December 31, 2021, and, accordingly, Wedbush did not perform either a discounted cash flow analysis or any multiples-based analyses with respect to Otic. With respect to the operating expense forecasts of Otic, upon the advice of Tokai and Otic, Wedbush assumed that such projections were reasonably prepared on a basis reflecting the best currently available estimates and judgments of the management of Otic as to the future operating expenses of Otic and that Otic will perform substantially in accordance with such projections. Wedbush further assumed no responsibility for and expressed no view as to any such projections or the assumptions on which they are based. Wedbush did not evaluate the solvency or fair value of Tokai, Otic, or any of their subsidiaries (or the impact of the transactions contemplated by the Share Purchase Agreement thereon) under any law relating to bankruptcy, insolvency or similar matters.

[Table of Contents](#)

Wedbush's opinion was based on economic, market and other conditions as in effect on, and the information made available to Wedbush as of, the date of such opinion. Wedbush also relied on the accuracy and completeness of Tokai's and Otic's representations and warranties in the Share Purchase Agreement, without regard to any qualifications that may be set forth in disclosure schedules or any other such qualifications. In addition, Wedbush assumed that the transaction will be consummated in accordance with the terms set forth in the Share Purchase Agreement without any waiver, amendment or delay of any terms or conditions that would be material to Wedbush's analysis. Representatives of Tokai advised Wedbush that, and Wedbush further assumed that, the final terms of the Share Purchase Agreement would not differ from the terms set forth in the draft reviewed by Wedbush in any respect material to Wedbush's analysis. Wedbush noted that events occurring after the date of its opinion could materially affect the assumptions used in preparing its opinion. Wedbush did not undertake any obligation to reaffirm or revise its opinion or otherwise comment upon any events occurring after the date of such opinion.

Wedbush is not a legal, tax or regulatory advisor, and did not express any opinion as to any tax or other consequences that may arise from the transactions contemplated by the Share Purchase Agreement, nor does its opinion address any legal, regulatory or accounting matters, as to which Wedbush understood that Tokai had obtained such advice as it deemed necessary from qualified professionals. Wedbush is a financial advisor only and relied upon, without independent verification, the assessment of Tokai and Otic and their legal, tax or regulatory advisors with respect to legal, tax or regulatory matters. Wedbush assumed that the transaction will have the tax effects contemplated by the Share Purchase Agreement.

Wedbush is an investment banking firm and a member of The New York Stock Exchange and other principal stock exchanges in the United States, and is regularly engaged as part of its business in the valuation of businesses and their securities in connection with mergers and acquisitions, negotiated underwritings, private placements, secondary distributions of listed and unlisted securities, and valuations for corporate, estate and other purposes. Wedbush was selected by Tokai based on Wedbush's experience, expertise and reputation and its familiarity with Tokai. The Tokai board of directors did not impose any limitations on Wedbush with respect to the investigations made or procedures followed in rendering its opinion. Wedbush's opinion was approved by a fairness committee at Wedbush in accordance with the requirements of FINRA Rule 5150.

In rendering its opinion, Wedbush expressed no opinion as to the amount or nature of any compensation to any officers, directors, or employees of Tokai, or any class of such persons, whether relative to the exchange ratio or otherwise, or with respect to the fairness of any such compensation.

Wedbush was not asked to, nor did it, offer any opinion as to the terms, other than the exchange ratio in connection with the transaction to the extent expressly set forth in Wedbush's opinion, of the Share Purchase Agreement, the amount of consideration to be paid or the form of the transaction. Wedbush did not express any opinion with respect to the terms of any other agreement entered into or to be entered into in connection with the transaction. Wedbush expressed no opinion as to the price at which shares of Tokai common stock may trade at any time subsequent to the announcement or consummation of the transaction. Wedbush also assumed that all governmental, regulatory or other consents and approvals necessary for the consummation of the transaction will be obtained without imposition of any terms or conditions that would be material to Wedbush's analysis.

Tokai paid Wedbush a \$50,000 retainer upon execution of its engagement letter and has agreed to pay Wedbush a fee of \$0.5 million for rendering its opinion, which became payable upon the delivery of Wedbush's opinion. Tokai has also agreed to pay Wedbush an additional fee of \$1 million, contingent upon closing of the transaction and against which the \$50,000 retainer and \$0.5 million opinion fee will be credited. In addition, Tokai has agreed to indemnify Wedbush for certain liabilities arising out of its engagement and has agreed to reimburse Wedbush for its expenses, including attorney's fees and disbursements. In the two years prior to the date of its opinion, Wedbush has not provided any services to Tokai or Otic. Wedbush may in the future provide investment banking and financial advisory services to Tokai, Otic and their respective affiliates for which services Wedbush would expect to receive compensation.

[Table of Contents](#)

In the ordinary course of its business, Wedbush and its affiliates may actively trade the common stock of Tokai or other instruments or obligations of Tokai for their own accounts and for the accounts of their customers and, accordingly, Wedbush and its affiliates may at any time hold a long or short position in the common stock of Tokai or such other instruments or obligations of Tokai.

Summary of Analyses

The following is a summary of the material financial analyses performed by Wedbush in connection with reaching its opinion:

- Public Market Equity Value Analysis with respect to Tokai;
- Liquidation Value Analysis with respect to Tokai;
- Public Company Market Valuation Analysis with respect to Otic;
- Precedent Merger and Acquisition Transaction Analysis with respect to Otic; and
- Precedent Initial Public Offering Analysis with respect to Otic.

The following summaries are not a comprehensive description of Wedbush's opinion or the analyses and examinations conducted by Wedbush, and the preparation of an opinion necessarily is not susceptible to partial analysis or summary description. Wedbush believes that such analyses and the following summaries must be considered as a whole and that selecting portions of such analyses and of the factors considered, without considering all such analyses and factors, would create an incomplete view of the process underlying the analyses. The order in which the analyses are described below does not represent the relative importance or weight given to the analyses by Wedbush. Some of the summaries of financial analyses below include information presented in tabular format. In order to fully understand the analyses, the tables must be read together with the text of each summary. The tables alone do not constitute a complete description of Wedbush's analyses. Considering the data described below without considering the full narrative description of the financial analyses, including the methodologies and assumptions underlying the analyses, could create a misleading or incomplete view of the analyses.

Additionally, the relative percentage ownership of the combined company was derived using respective stipulated values of Otic of approximately \$50.0 million and Tokai of approximately \$33.0 million. These amounts were negotiated by the parties as the respective valuations of each party and are not specifically set forth in the Share Purchase Agreement. Based on the outstanding share capital of Otic as of the date of the Share Purchase Agreement and the shares issuable upon exercise of warrants to purchase shares of Otic and the conversion of certain outstanding debt facilities of Otic into shares of Otic that are expected to be exercised or converted prior to the closing of the Otic Transaction, Tokai expects to issue _____ shares of Tokai common stock in the Otic Transaction. If all of Otic's outstanding options and warrants are exercised prior to closing, Tokai will issue a total of 36,911,631 shares of Tokai common stock in the Otic Transaction. Following the closing of the Otic Transaction, the stockholders of Otic are expected to hold approximately 60% of the outstanding shares of Tokai common stock, excluding for this purpose the effect on ownership of the issuance of shares in the Equity Financing.

Depending on the total number of shares of Otic capital stock outstanding as of immediately prior to the closing (which is subject to change primarily due to the potential exercise of convertible securities prior to the closing), the relative percentage ownership of the combined company following the consummation of the Transaction could be in the range of approximately 58% to 62% by the Otic securityholders and approximately 38% to 42% by the Tokai securityholders. The data described below assumes that the relative percentage ownership of the combined company following the consummation of the Transaction will be approximately 60% by the Otic securityholders and approximately 40% by the Tokai securityholders.

In performing its analyses, Wedbush made numerous assumptions with respect to industry performance and general business and economic conditions such as industry growth, inflation, interest rates and many other

[Table of Contents](#)

matters, many of which are beyond the control of Tokai, Otic and Wedbush. Any estimates contained in Wedbush's analyses are not necessarily indicative of actual values or future results, which may be significantly more or less favorable than suggested by such analyses.

Wedbush noted that it was Tokai management's view that a discounted cash flow analysis was not an appropriate method of valuing Tokai because Tokai had ceased all product research and development and therefore did not have any anticipated future revenues to form a basis for such an analysis. Accordingly, Wedbush did not conduct a discounted cash flow analysis and instead relied on the other analyses described herein.

Wedbush did not perform a discounted cash flow analysis or any multiples-based analyses for Otic because Wedbush was not provided, and Wedbush did not otherwise have access to, financial forecasts regarding Otic's business, other than certain expense forecasts for the five years ending December 31, 2021. Further, Wedbush believed that such analyses were not appropriate because Otic is a clinical stage company with no marketed products and it will not have any revenues until its product candidates are approved for marketing by the FDA, which will require the successful completion of ongoing or planned Phase 2 trials and future Phase 3 trials.

Except as otherwise noted, the following quantitative information, to the extent that it is based on market data, is based on market data as it existed on or before December 20, 2016 and is not necessarily indicative of current market conditions.

Public Market Equity Value Analysis—Tokai

Using publicly available information, Wedbush noted that the volume weighted average trading price for the Tokai common stock was \$1.02 per share on December 20, 2016, \$1.03 per share for the one week ended December 20, 2016 and \$1.07 per share for the one month ended December 20, 2016. Based upon these volume weighted average trading prices for the Tokai common stock and the number of fully diluted outstanding shares of Tokai common stock as provided by management of Tokai, Wedbush calculated Tokai's equity value as approximately \$23.2 million to \$24.3 million.

Liquidation Value Analysis—Tokai

Wedbush reviewed information prepared by Tokai management regarding Tokai's liquidation value. Based upon Tokai's cash balance of approximately \$38.3 million as of August 31, 2016 and Tokai management's estimates of future liabilities with respect to clinical obligations, pending litigation, insurance and legal costs, other corporate expenses, lease expenses, compensation and severance expenses and debt repayment expenses, Wedbush noted that Tokai management estimated that Tokai would have a liquidation value of approximately \$19.3 million as of August 31, 2017.

Public Company Market Valuation Analysis—Otic

Wedbush reviewed publicly available information relating to the following publicly-traded companies with an aggregate market capitalization between \$33 million and \$1 billion in the biopharmaceutical industry with Phase 1 product candidates (and no product candidates beyond Phase 1 or Phase 1/2) that as of December 20, 2016 did not have human efficacy data (the "***Phase 1 Companies***"), which criteria were applied to select for companies similar to Otic:

- Regenxbio Inc.;
- Protagonist Therapeutics, Inc.;
- Voyager Therapeutics;
- Ra Pharmaceuticals, Inc.;

[Table of Contents](#)

- Proteostasis Therapeutics, Inc.;
- Madrigal Pharmaceuticals, Inc.;
- Applied Genetic Technologies Corporation;
- KalVista Pharmaceuticals, Inc.; and
- Dimension Therapeutics, Inc.

Wedbush noted that, although such companies had certain financial and operating characteristics that could be considered similar to those of Otic, none of the companies had the same management, make-up, technology, size or mix of business as Otic and, accordingly, there were inherent limitations on the applicability of such companies to the valuation analysis of Otic.

Wedbush calculated the aggregate market capitalization of each of the selected companies based upon the closing price of the common stock of each selected company on December 20, 2016 and the fully-diluted number of shares outstanding, using the treasury stock method. The results of this analysis are summarized as follows:

	Market Capitalization at December 20, 2016 (\$ in millions)
	Phase 1 Companies
Mean	\$ 287.2
Median	\$ 302.0

Wedbush calculated the implied ownership of holders of Tokai common stock in the combined company based upon the approximate \$33.0 million value attributed to the Tokai common stock and the approximate \$50.0 million value attributed to the Otic common stock pursuant to the exchange ratio in connection with the transaction, and the mean and median values described above.

The results of this analysis are summarized as follows:

	Public Company Market Valuation Analysis			
	Equity Value (\$ in millions)	Ownership		
Otic Equity Value per Share Purchase Agreement	\$ 50.0	60%		
Tokai Equity Value per Share Purchase Agreement	\$ 33.0	40%		
Aggregate Value per Share Purchase Agreement	\$ 83.0	100%		
	Mean		Median	
	Equity Value (\$ in millions)	Ownership	Equity Value (\$ in millions)	Ownership
Otic Equity Value per Public Company Market Valuation Analysis	\$ 287.2	90%	\$ 302.0	90%
Tokai Equity Value per Share Purchase Agreement	\$ 33.0	10%	\$ 33.0	10%
Implied Aggregate Value	\$ 320.2	100%	\$ 335.0	100%

Wedbush noted that the implied ownership percentage of holders of Tokai common stock based upon the approximate \$33.0 million value attributed to the Tokai common stock and the approximate \$50.0 million

[Table of Contents](#)

value attributed to the Otic common stock pursuant to the exchange ratio in connection with the transaction was higher than the implied ownership percentages derived based upon the mean and median equity values attributed to Otic described above.

Precedent Merger and Acquisition Transaction Analysis—Otic

Wedbush reviewed publicly available information relating to the following acquisitions of private companies in the biopharmaceutical industry considered by Wedbush to be similar to Otic, which had Preclinical and Phase 1 product candidates (and no product candidates beyond Phase 1 or Phase 1/2) that did not have human efficacy data at the time of announcement of the transaction, with an aggregate valuation (based solely upon upfront payments and excluding contingent value rights or other post-closing payments) of between \$33 million and \$1.0 billion and announced between May 2014 and September 2016 (the “*Selected Transactions*”):

Announcement Date	Target	Acquiror
September 6, 2016	RetroSense Therapeutics	Allergan plc
August 1, 2016	Bamboo Therapeutics	Pfizer
July 5, 2016	Cormorant Pharmaceuticals	Bristol-Myers Squibb
December 23, 2015	PhosImmune	Agenus
October 21, 2015	Admune Therapeutics	Novartis AG
October 9, 2015	Adheron Therapeutics	Roche Holding AG
July 28, 2015	cCAM Biotherapeutics	Merck & Co.
May 1, 2014	Fibrotech Therapeutics Pty	Shire plc

Wedbush noted that although the companies that were acquired in the Selected Transactions had certain financial and operating characteristics that could be considered similar to those of Otic, none of such companies had the same management, make-up, technology, size or mix of business as Otic and, accordingly, there were inherent limitations on the applicability of such companies to the valuation analysis of Otic. Wedbush also noted that market conditions have varied over the precedent time periods.

Wedbush calculated the aggregate value of each of the target companies in the Selected Transactions (based solely upon upfront payments and excluding contingent value rights or other post-closing payments). The results of this analysis are summarized as follows:

	Valuation (\$ in millions)
Mean	\$ 89.1
Median	\$ 85.0

Wedbush calculated the implied ownership of holders of Tokai common stock in the combined company based upon the approximate \$33.0 million value attributed to the Tokai common stock and the approximate \$50.0 million value attributed to the Otic common stock pursuant to the exchange ratio in connection with the transaction, and the mean and median values described above.

The results of this analysis are summarized as follows:

	Merger and Acquisition Transaction Analysis	
	Equity Value	Ownership
Otic Equity Value per Share Purchase Agreement	\$50.0	60%
Tokai Equity Value per Share Purchase Agreement	\$33.0	40%
Aggregate Value per Share Purchase Agreement	\$83.0	100%

[Table of Contents](#)

	Mean		Median	
	Equity Value (\$ in millions)	Ownership	Equity Value (\$ in millions)	Ownership
Otic Equity Value per Merger and Acquisition Transaction Analysis	\$ 89.1	73%	\$ 85.0	72%
Tokai Equity Value per Share Purchase Agreement	\$ 33.0	27%	\$ 33.0	28%
Implied Aggregate Value	\$ 122.1	100%	\$ 118.0	100%

Wedbush noted that the implied ownership percentage of holders of Tokai common stock based upon the approximate \$33.0 million value attributed to the Tokai common stock and the approximate \$50.0 million value attributed to the Otic common stock pursuant to the exchange ratio in connection with the transaction was higher than the implied ownership percentages derived based upon the mean and median equity values attributed to Otic described above.

Precedent Initial Public Offering Analysis—Otic

Wedbush reviewed publicly available information relating to the following initial public offerings of companies in the biopharmaceutical industry which had Phase 1 product candidates (and no product candidates beyond Phase 1 or Phase 1/2) that did not have human efficacy data at the time of initial public offering, which raised a minimum of \$20.0 million in gross proceeds, and which priced between January 2014 and November 2016 (the “*Phase 1 IPOs*”), which criteria were applied to select for companies similar to Otic:

Pricing Date	Issuer
August 10, 2016	Protagonist Therapeutics, Inc.
October 25, 2016	Ra Pharmaceuticals, Inc.
March 22, 2016	Corvus Pharmaceuticals, Inc.
February 10, 2016	Proteostasis Therapeutics, Inc.
November 10, 2015	Voyager Therapeutics, Inc.
October 28, 2015	MyoKardia, Inc.
October 21, 2015	Dimension Therapeutics, Inc.
June 16, 2015	Nivalis Therapeutics, Inc.
May 6, 2015	aTyr Pharma, Inc.
July 31, 2014	Loxo Oncology, Inc.

Wedbush noted that although such companies had certain financial and operating characteristics that could be considered similar to those of Otic, none of the companies had the same management, make-up, technology, size or mix of business as Otic and, accordingly, there were inherent limitations on the applicability of such companies to the valuation analysis of Otic. Wedbush also noted that market conditions have varied over the precedent time periods.

Wedbush calculated the fully diluted pre-money valuation of each of the companies that participated in the Phase 1 IPOs at the time of pricing of its initial public offering using the treasury stock method, which (i) includes the conversion of all outstanding in-the-money warrants, options and convertible preferred stock into common stock and (ii) excludes the conversion of any employee stock incentive plans, employee stock option plans or other stock awarded to employees or directors of such companies. The results of this analysis are summarized as follows:

	Pre- Money Valuation (\$ in millions)
	Phase 1 IPOs
Mean	\$ 191.6
Median	\$ 187.7

[Table of Contents](#)

Wedbush calculated the implied ownership of holders of Tokai common stock in the combined company based upon the approximate \$33.0 million value attributed to the Tokai common stock and the approximate \$50.0 million value attributed to the Otic common stock pursuant to the exchange ratio in connection with the transaction, and the mean and median values described above.

The results of this analysis are summarized as follows:

	Initial Public Offering Analysis			
	Equity Value	Ownership		
Otic Equity Value per Share Purchase Agreement	\$ 50.0	60%		
Tokai Equity Value per Share Purchase Agreement	\$ 33.0	40%		
Aggregate Value per Share Purchase Agreement	\$ 83.0	100%		

	Mean		Median	
	Equity Value (\$ in millions)	Ownership	Equity Value (\$ in millions)	Ownership
Otic Equity Value per Initial Public Offering Analysis	\$ 191.6	85%	\$ 187.7	85%
Tokai Equity Value per Share Purchase Agreement	\$ 33.0	15%	\$ 33.0	14%
Implied Aggregate Value	\$ 224.6	100%	\$ 220.7	100%

Wedbush noted that the implied ownership percentage of holders of Tokai common stock based upon the approximate \$33.0 million value attributed to the Tokai common stock and the approximate \$50.0 million value attributed to the Otic common stock pursuant to the exchange ratio in connection with the transaction was higher than the implied ownership percentages derived based upon the mean and median equity values attributed to Otic described above.

Miscellaneous

This summary is not a complete description of Wedbush's opinion or the underlying analyses and factors considered in connection with Wedbush's opinion. The preparation of a fairness opinion is a complex process involving the application of subjective business and financial judgment in determining the most appropriate and relevant methods of financial analysis and the application of those methods to the particular circumstances and, therefore, is not readily susceptible to partial analysis or summary description. Wedbush believes that its analyses described above must be considered as a whole and that considering any portion of such analyses and of the factors considered without considering all analyses and factors could create a misleading view of the process underlying its opinion. Selecting portions of the analyses or summary set forth above, without considering the analyses as a whole, could create an incomplete view of the processes underlying the Wedbush opinion. In arriving at its fairness determination, Wedbush considered the results of all of its analyses and did not attribute any particular weight to any factor or analysis. Rather, it made its fairness determination on the basis of its experience and professional judgment after considering the results of all of its analyses. No company or transaction in the analyses described above is identical to Tokai, Otic or the transaction.

In conducting its analyses and arriving at its opinion, Wedbush utilized a variety of valuation methods. The analyses were prepared solely for the purpose of enabling Wedbush to provide its opinion to the Tokai board of directors as to the fairness of the exchange ratio in connection with the transaction, from a financial point of view, to the stockholders of Tokai as of the date of the opinion and do not purport to be an appraisal or necessarily reflect the prices at which businesses or securities actually may be sold, which are inherently subject to uncertainty.

[Table of Contents](#)

The terms of the transaction were determined through arm's-length negotiations between Tokai and Otic and were approved by the Tokai board of directors. Although Wedbush provided advice to the Tokai board of directors during the course of these negotiations, the decision to enter into the Share Purchase Agreement was solely that of the Tokai board of directors. Wedbush did not recommend any specific consideration to Tokai or the Tokai board of directors, or that any specific amount or type of consideration constituted the only appropriate consideration for the transaction. As described above, the opinion of Wedbush and its presentation to the Tokai board of directors were among a number of factors taken into consideration by the Tokai board of directors in making its determination to approve the Share Purchase Agreement, the transaction and the other transactions contemplated by the Share Purchase Agreement.

Material U.S. Federal Income Tax Consequences of the Transaction to Tokai Stockholders

Neither the Otic Transaction nor the related Equity Financing will result in any taxable gain or loss for U.S. federal income tax purposes to any Tokai stockholder in his, her or its capacity as a Tokai stockholder. Tokai stockholders who are also stockholders of Otic should consult their own tax advisors as to the tax consequences of them participating in the Otic Transaction with respect to their Otic stock.

Regulatory Approvals

Neither Tokai nor Otic is required to make any filings or to obtain approvals or clearances from any regulatory authorities in the United States or other countries to consummate the Otic Transaction contemplated by the Share Purchase Agreement. In Israel, Otic is required to prepare, file and receive all Israeli tax rulings with respect to the Otic Transaction, and Tokai is required to deliver to Otic an executed copy of an undertaking in the standard form required by the Office of the Chief Scientist from non-Israeli residents investing in Israeli companies which have received support from the OCS. In the United States, Tokai must comply with applicable federal and state securities laws and NASDAQ rules and regulations in connection with the issuance of shares of Tokai common stock in the Otic Transaction and the issuance of shares of Tokai common stock in the Equity Financing, including the filing with the SEC of this proxy statement.

Anticipated Accounting Treatment

Accounting Standards Codification Topic 805, *Business Combinations* ("**ASC 805**") requires the use of the acquisition method of accounting for business combinations. In applying the acquisition method, it is necessary to identify both the accounting acquiree and the accounting acquirer. Otic management has determined that Otic represents the accounting acquirer in the Otic Transaction based on an analysis of the criteria outlined in ASC 805 and the facts and circumstances specific to the transaction, including: (1) stockholders of Otic are expected to own approximately 60% of the voting interests of the combined company immediately following the closing of the Otic Transaction; (2) the majority of the board of directors of the combined company will be composed of directors designated by Otic, pursuant to the terms of the Share Purchase Agreement; and (3) existing members of Otic management will be the management of the combined company.

Because Otic has been determined to be the accounting acquirer in the Otic Transaction, but not the legal acquirer, the Otic Transaction is deemed a reverse acquisition under the guidance of ASC 805. As a result, upon consummation of the Otic Transaction, (1) the historical financial statements of Otic will become the historical financial statements of the combined company and (2) Otic will record the business combination in its financial statements and will apply the acquisition method to account for the acquired assets and assumed liabilities of Tokai as of the closing date of the transaction. Applying the acquisition method includes recording the identifiable assets acquired and liabilities assumed at their fair values, and recording goodwill for the excess of the purchase price over the aggregate fair value of the identifiable assets acquired and liabilities assumed, if any, or recording a bargain purchase gain if the aggregate fair value of the identifiable assets acquired and liabilities assumed exceeds the purchase price for the acquisition.

[Table of Contents](#)

The application of the acquisition method of accounting is dependent upon certain valuations and other studies that have yet to commence or progress to a stage where there is sufficient information for a definitive measurement of Tokai's assets to be acquired and liabilities to be assumed. A final determination of these estimated fair values, which cannot be made prior to the completion of the Otic Transaction, will be based on the actual net tangible and intangible assets of Tokai that exist as of the closing date of the Otic Transaction.

No Appraisal Rights

Holders of Tokai common stock will not be entitled to any dissenters' rights or appraisal rights with respect to any of the proposals to be voted on at the special meeting.

TERMS OF THE SHARE PURCHASE AGREEMENT

The following is a summary of the material terms of the Share Purchase Agreement. A copy of the Share Purchase Agreement is attached as Annex A to this proxy statement. The Share Purchase Agreement has been attached to this proxy statement to provide you with information regarding its terms. It is not intended to provide any other factual information about Tokai, Otic, or the Sellers. The following description does not purport to be complete and is qualified in its entirety by reference to the Share Purchase Agreement. You should refer to the full text of the Share Purchase Agreement for details of the Otic Transaction and the terms and conditions of the Share Purchase Agreement.

Explanatory Note Regarding the Share Purchase Agreement

The Share Purchase Agreement contains representations and warranties that Tokai, on the one hand, and Otic and the Sellers, on the other hand, have made to one another as of specific dates. These representations and warranties have been made for the benefit of the other parties to the Share Purchase Agreement and may be intended not as statements of fact but rather as a way of allocating the risk to one of the parties if those statements prove to be incorrect. Moreover, certain of those representations and warranties may not be accurate or complete as of any specified date, may be subject to a contractual standard of materiality different from those generally applicable to SEC filings or may have been used for purposes of allocating risk among the parties to the Share Purchase Agreement, rather than establishing matters of fact. In addition, the assertions embodied in the representations and warranties are qualified by information in confidential disclosure schedules exchanged by the parties in connection with signing the Share Purchase Agreement. While Tokai, Otic and the Sellers do not believe that these disclosure schedules contain information required to be publicly disclosed under applicable securities laws, other than information that has already been so disclosed, the disclosure schedules do contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the attached Share Purchase Agreement. Accordingly, you should not rely on the representations and warranties as current characterizations of the actual state of facts or conditions of Tokai, Otic or the Sellers, because they were made as of specific dates, may be intended merely as a risk allocation mechanism among Tokai, Otic and the Sellers and are modified by the disclosure schedules.

The Otic Transaction Structure

Upon the terms and subject to the conditions set forth in the Share Purchase Agreement, Tokai will acquire all of the ordinary and preferred shares of Otic in exchange for the issuance to the Sellers of a number of shares of Tokai common stock determined pursuant to the exchange ratio set forth in the Share Purchase Agreement and below in the section entitled “*Terms of the Share Purchase Agreement—Exchange Ratio*,” beginning on page 98 of this proxy statement.

The issuance of Tokai common stock to the Sellers will be issued in transactions exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, and Regulation D or Regulation S promulgated thereunder and may not be offered or sold by the holders of those shares absent registration or an applicable exemption from registration requirements.

Subject to the terms and conditions of the Share Purchase Agreement, it is currently anticipated that at closing, the Sellers will collectively receive approximately _____ shares of Tokai common stock. Also in connection with the Otic Transaction, Tokai will assume the (i) outstanding share options of Otic, and (ii) outstanding warrants of Otic, each of which will be adjusted to reflect the exchange ratio for the Otic Transaction, as described below in the section entitled “*Effect of the Otic Transaction on Otic Share Options, Otic Warrants and Tokai Stock Options—Otic Share Options and Otic Warrants*,” beginning on page 98 of this proxy statement. Following the Otic Transaction, Otic will be a wholly owned subsidiary of Tokai, and the Sellers are expected to hold approximately 60% of the outstanding shares of Tokai common stock, and the current Tokai stockholders are expected to own approximately 40% of the outstanding shares of Tokai common stock.

[Table of Contents](#)

Consideration

At the closing of the Otic Transaction, each Seller will deliver to Tokai its Otic share certificates (or an affidavit for any lost, stolen, destroyed or never issued share certificate(s)) and related documents necessary for transfer of such share certificates in respect of Otic shares, and in exchange therefor, Tokai will deliver to each Seller stock certificates representing the number of shares of Tokai common stock that the Seller has the right to receive pursuant to the terms of the Share Purchase Agreement.

The number of shares of Tokai common stock that the Sellers in the aggregate will have the right to receive will be determined pursuant to the exchange ratio set forth in the Share Purchase Agreement as described below in the section entitled “*Terms of the Share Purchase Agreement—Exchange Ratio*,” beginning on page 98 of this proxy statement.

The market value of the shares of Tokai common stock issued pursuant to the Share Purchase Agreement will depend on the market value of the shares of Tokai common stock at the time the Otic Transaction closes, and could vary significantly from the market value on the date of this proxy statement.

No fractional shares of Tokai common stock will be issuable pursuant to the Share Purchase Agreement to the Sellers, and no certificates or scrip for any fractional shares will be issued. Any fractional shares shall be rounded down to the nearest whole share, and no cash payment will be made in respect of such rounding.

Exchange Ratio

The number of shares of Tokai common stock that the Sellers in the aggregate will receive at closing in exchange for such Sellers’ Otic shares is determined pursuant to the exchange ratio as set forth in the Share Purchase Agreement, and which was calculated based upon the relative stipulated values of each of Tokai and Otic.

The exchange ratio is 4.255. Accordingly, at closing, the Sellers in the aggregate will receive 4.255 shares of Tokai common stock for each Otic ordinary and preferred share. The actual number of shares of Tokai common stock that a Seller will receive at closing depends on an allocation schedule that Otic will deliver to Tokai prior to closing. The exchange ratio does not reflect the proposed reverse stock split

Effect of the Otic Transaction on Otic Share Options, Otic Warrants and Tokai Stock Options

Otic Share Options and Otic Warrants

Pursuant to the Share Purchase Agreement, at closing Tokai will assume the outstanding share option awards and warrants of Otic (other than warrants of Otic that are exercised in connection with the Otic Transaction). Each of these options and warrants will be adjusted to reflect a ratio of _____ shares of Tokai common stock for each Otic share. Accordingly, at closing, each of Otic’s outstanding share option awards and warrants will become exercisable, as the case may be, for or into _____ shares of Tokai common stock for each Otic share it was previously exercisable for, at a correspondingly adjusted exercise price, provided that the exercise price of such stock options and warrants will be rounded down to the nearest whole share and the exercise prices will be rounded up to the nearest cent, and no cash payment will be made in respect of such rounding. After giving effect to the exchange ratio, and assuming no exercise of, or other change in the number of, outstanding share option awards and warrants of Otic, Tokai will assume options to purchase _____ shares of Tokai common stock at a weighted average exercise price of \$ _____ per share and warrants to purchase _____ shares of Tokai common stock at a weighted average exercise price of \$ _____ per share. If all of these options and warrants were exercised prior to the closing of the Otic Transaction, Tokai would issue 36,911,631 shares of common stock and the Otic shareholders would own approximately 62% of the outstanding shares of Tokai common stock.

[Table of Contents](#)

Tokai Options

Upon closing of the Otic Transaction, all of Tokai's outstanding stock options will remain outstanding and in effect. Tokai's board of directors has determined that the Otic Transaction constitutes a change in control for purposes of Tokai's stock options. As a result, if any holder of Tokai stock options (other than Tokai's non-employee directors) is terminated without cause or resigns for good reason following the closing, such holder's stock options will immediately vest in full. Stock options held by Tokai's non-employee directors will vest in full immediately upon the change in control.

Directors and Officers of Tokai Following the Otic Transaction

Immediately following the completion of the Otic Transaction, the executive management team of the combined company is expected to be composed of the current executive team of Otic: Gregory J. Flesher, serving as President and Chief Executive Officer, Christine G. Ocampo, serving as Chief Financial and Compliance Officer, and Dr. Catherine C. Turkel, Chief Development Officer.

In accordance with Tokai's certificate of incorporation and by-laws, the Tokai board of directors currently consists of seven directors divided into three staggered classes, with one class to be elected at each annual meeting to serve for a three-year term. The staggered structure of the board of directors will remain in place for the combined company following the consummation of the Otic Transaction. At Tokai's most recent annual stockholders meeting, held in 2016, Class II directors were elected. As a result, the term of the Class II directors of the combined company is set to expire upon the election and qualification of successor directors at the Tokai annual stockholders meeting in 2019, and the terms of the Class III and Class I directors will expire upon the election and qualification of successor directors at the annual stockholders meetings in 2017 and 2018, respectively.

The director classes for Tokai are currently as follows:

- Class I directors (term ending in 2018): Cheryl L. Cohen, Jodie P. Morrison and Joseph A. Yanchik, III;
- Class II directors (term ending in 2019): David A. Kessler; and
- Class III director (term ending in 2017): Seth L. Harrison and Stephen Buckley, Jr.

The combined company's board of directors will initially be fixed at seven members, consisting of (i) four members designated by Otic: Keith A. Katkin as Chairman, Gregory J. Flesher, Gary A. Lyons and Erez Chimovits and (ii) three board members designated by Tokai, which may include existing board members and up to one new member designated by Tokai.

Pursuant to the terms of the Share Purchase Agreement, it is anticipated that these directors will be appointed to the three staggered director classes of the combined company's board of directors as follows:

- Class I directors (term ending 2018):
- Class II directors (term ending 2019):
- Class III directors (term ending 2017):

Conditions to the Consummation of the Otic Transaction

Each party's obligation to consummate the Otic Transaction is subject to the satisfaction or waiver by each of the parties, at or prior to the Otic Transaction, of various conditions, which include the following:

- the approval of the issuance of Tokai common stock in the Otic Transaction by the requisite vote of stockholders under applicable law and stock market regulation;

[Table of Contents](#)

- the filing, obtainment or occurrence of all authorizations and consents, including Israeli tax rulings set forth in the Share Purchase Agreement, orders or approvals of, or declarations or filings with, or expirations of waiting periods imposed by any governmental entity in connection with the Otic Transaction, the failure of which to file, obtain or occur is reasonably likely to have a Tokai Material Adverse Effect or an Otic Material Adverse Effect (as such terms are defined in the Share Purchase Agreement) shall have been filed, been obtained or occurred on terms that would not reasonably be likely to have a Tokai Material Adverse Effect or an Otic Material Adverse Effect;
- the absence of any order, executive order, stay, decree, judgment or injunction (preliminary or permanent) or statute, rule, or regulation which is in effect and has the effect of making the Otic Transaction illegal or otherwise prohibiting consummation of the Otic Transaction; and
- the approval of the NASDAQ Listing Application—For Companies Conducting a Business Combination that Results in a Change of Control with respect to the shares of Tokai common stock to be issued pursuant to the Share Purchase Agreement.

In addition, the obligation of Tokai to consummate the Otic Transaction is further subject to the satisfaction or waiver of the following conditions:

- the truth and correctness of all representations and warranties of Otic and the Sellers in the Share Purchase Agreement on the date of the Share Purchase Agreement and on the closing date of the Otic Transaction with the same force and effect as if made on the date on which the Otic Transaction is to be completed or, if such representations and warranties address matters as of a particular date, then as of that particular date, except where the failure of these representations and warranties to be true and correct, individually or in the aggregate, would not reasonably be expected to have an Otic Material Adverse Effect;
- the performance or compliance in all material respects of Otic and the Sellers with all of its or their covenants and obligations in the Share Purchase Agreement;
- the absence of any continuing Otic Material Adverse Effect;
- the delivery by Otic of resignations of each director of Otic and its subsidiaries; and
- the delivery by Otic of certain customary closing deliverables required under the Share Purchase Agreement.

In addition, the obligations on the part of Otic to consummate the Otic Transaction are further subject to the satisfaction or waiver of the following conditions:

- the truth and correctness of all representations and warranties of Tokai in the Share Purchase Agreement on the date of the Share Purchase Agreement and on the closing date of the Otic Transaction with the same force and effect as if made on the date on which the Otic Transaction is to be completed or, if such representations and warranties address matters as of a particular date, then as of that particular date, except where the failure of these representations and warranties to be true and correct, individually or in the aggregate, would not reasonably be expected to have a Tokai Material Adverse Effect;
- the performance or compliance in all material respects of Tokai with all of its covenants and obligations in the Share Purchase Agreement;
- the absence of any continuing Tokai Material Adverse Effect;
- the delivery by Tokai of resignations of each director of Tokai who will not continue to serve in such roles after closing;
- the preparation, filing and receipt by Otic of all Israeli tax rulings with respect to the transactions contemplated by the Share Purchase Agreement;

[Table of Contents](#)

- the delivery by Tokai to Otic an executed copy of an undertaking in the standard form required by the Office of the Chief Scientist from non-Israeli residents investing in Israeli companies which have received support from the Office of the Chief Scientist, substantially in the form attached to the Share Purchase Agreement; and
- the delivery by Tokai of certain customary closing deliverables required under the Share Purchase Agreement.

Representations and Warranties

The Share Purchase Agreement contains representations and warranties of Tokai and Otic customary for a transaction of this type relating to, among other things: corporate organization, standing, power and similar corporate matters; capitalization; subsidiaries; authority; no conflict; required filings and consents; financial statements and information provided, and with respect to Tokai, documents filed with the SEC and the accuracy of information contained in those documents; no undisclosed liabilities; absence of certain changes or events; taxes; owned and leased real properties; intellectual property; contracts; litigation; environmental matters; employee benefit plans; compliance with laws; permits and regulatory matters; employees; insurance; the inapplicability of section 203 of the DGCL; broker fees; controls and procedures, certifications and other matters; books and records; and the absence of representations and warranties of the other parties except for those representations and warranties contained in the Share Purchase Agreement; for Tokai, the opinion of its financial advisor; and for Otic, the absence of a fairness opinion; business relationships with affiliates; government funding; export control laws; privacy and data security; and ownership of Tokai common stock.

In addition, the Share Purchase Agreement contains representations and warranties of the Sellers relating to, among other things: corporate organization, authority, power and similar corporate matters; legal and beneficial ownership of and good title to the Otic shares; litigation; broker fees; entry into the Share Purchase Agreement on each Seller's own account, without a view toward resale or distribution; status as accredited investor or a non-"U.S. person" under Regulation S of the Securities Act, sophistication and ability to bear the economic risk of investing in the Otic Transaction; access to information about Tokai and Otic; resale restrictions; and the absence of representations and warranties of the other parties except for those representations and warranties contained in the Share Purchase Agreement.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the Otic Transaction, but their accuracy forms the basis of one of the conditions to the obligations of Tokai, Otic and the Sellers to consummate the Otic Transaction.

No Solicitation; Third Party Competing Proposal

Each of Tokai and Otic agreed that, except as described below, Tokai and Otic will not, nor will either party authorize or permit any of the officers, directors, employees, financial advisors, attorneys, accountants, consultants, agents and other authorized representatives of such party, acting in such capacity (collectively, "*representatives*"), to, directly or indirectly:

- solicit, seek or initiate or knowingly take any action to facilitate or encourage any offers, inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, any "acquisition proposal" (as defined below);
- enter into, continue or otherwise participate or engage in any discussions or negotiations regarding any acquisition proposal, or furnish to any person any non-public information or afford any person other than Tokai or Otic, as applicable, access to such party's property, books or records (except pursuant to a request by a governmental entity) in connection with any acquisition proposal;
- take any action to make the provisions of any takeover statute inapplicable to any transactions contemplated by an acquisition proposal; or

Table of Contents

- publicly propose to do any of the foregoing.

An “**acquisition proposal**” means, with respect to Tokai or Otic:

any inquiry, proposal or offer for:

- a merger, consolidation, dissolution, sale of substantial assets, recapitalization, share exchange, tender offer or other business combination involving such party and its subsidiaries (other than mergers, consolidations, recapitalizations, share exchanges or other business combinations involving solely such party and/or one or more subsidiaries of such party);
- any proposal for the issuance by such party of 15% or more of its equity securities; or
- any proposal or offer to acquire in any manner, directly or indirectly, 15% or more of the equity securities or consolidated total assets of such party and its subsidiaries, in each case other than the transactions contemplated by the Share Purchase Agreement.

However, Tokai and its representatives may:

- furnish non-public information to, and may enter into discussions or negotiations with, any “qualified person” (as defined below) and its representatives, pursuant to a confidentiality agreement not materially less restrictive with respect to the confidentiality obligations of the qualified person than the confidentiality agreement between Tokai and Otic;
- engage in discussions or negotiations (including solicitation of revised acquisition proposals) with any qualified person (and the representatives of such qualified person) regarding any such acquisition proposal; or
- amend, or grant a waiver or release under, any standstill or similar agreement with respect to any capital stock of such party with any qualified person.

A “**qualified person**” means any person making an unsolicited acquisition proposal that the Tokai board of directors determines in good faith (after consultation with outside counsel and its financial advisors) is, or could reasonably be expected to lead to, a “superior proposal,” (as defined below) and such acquisition proposal has not resulted from a material breach by Tokai of its “no solicitation” obligations under the Share Purchase Agreement.

A “**superior proposal**” means, with respect to Tokai, any *bona fide*, unsolicited written proposal made by a third party to acquire 50% or more of the equity securities or consolidated total assets of such party and its subsidiaries, pursuant to a tender or exchange offer, a merger, a consolidation, business combination or recapitalization or a sale or exclusive license of its assets, (a) on terms which the board of directors of such party determines in its good faith judgment to be more favorable to the holders of such party’s capital stock than the transactions contemplated by the Share Purchase Agreement (after consultation with its financial and legal advisors), taking into account all the terms and conditions of such proposal and the Share Purchase Agreement (including any termination or break-up fees and conditions to consummation, as well as any written, binding offer by the other party hereto to amend the terms of the Share Purchase Agreement, which offer is not revocable for at least three business days) that the board of directors of such party determines to be relevant and (b) which board of directors of such party has determined to be reasonably capable of being completed on the terms proposed, taking into account all financial, regulatory, legal and other aspects of such proposal that board of directors of such party determines to be relevant (including the likelihood and timing of consummation (as compared to the transactions contemplated by the Share Purchase Agreement)).

The Share Purchase Agreement also provides that each party will promptly advise the other party of its receipt of any acquisition proposal and provide to the other party a copy of such acquisition proposal (if written), or a summary of the material terms and conditions of such acquisition proposal (if oral), including the identity of the person making the acquisition proposal, and copies of all written communications with such person making

[Table of Contents](#)

such acquisition proposal. Such party in receipt of an acquisition proposal shall notify the other party, in writing, of any decision of its board of directors as to whether to consider any acquisition proposal or to enter into discussions or negotiations concerning any acquisition proposal or to provide non-public information with respect to such to any person, which notice shall be given as promptly as practicable after such determination was reached (and in any event no later than one business day after such determination was reached). Such party in receipt of an acquisition proposal will:

- provide the other party with written notice setting forth such information as is reasonably necessary to keep the other party informed in all material respects of the status and material terms of any such acquisition proposal and of any material amendments or modifications thereto;
- keep such other party informed as promptly as practicable with respect to any changes to the material terms of an acquisition proposal submitted to such party (and in any event within twenty-four hours following any such changes), including by providing a copy of all written proposals and a summary of all oral proposals or material oral modifications to an earlier written proposal, in each case relating to any acquisition proposal;
- prior to, or substantially concurrently with, the provision of any non-public information of such party to any such person, provide such information to the other party (including by posting such information to an electronic data room), to the extent such information has not previously been made available to the other party; and
- promptly (and in any event within twenty-four hours of such determination) notify the other party of any determination by such party's board of directors that such acquisition proposal constitutes a superior proposal

Changes to Board Recommendation

Pursuant to the Share Purchase Agreement, the Tokai board of directors has agreed to recommend that Tokai's stockholders vote to approve the issuance of Tokai common stock in the Otic Transaction and to take all action that is both reasonable and lawful to solicit from its stockholders proxies in favor of the issuance of Tokai common stock in the Otic Transaction. Further, prior to the earlier to occur of (a) the closing, and (b) the time at which the Share Purchase Agreement is terminated in accordance with its terms:

- the Tokai board of directors shall not withhold, withdraw or modify, or publicly propose to withdraw or modify, its approval or recommendation with respect to the issuance of Tokai common stock in the Otic Transaction (a "*recommendation change*");
- each of Tokai and Otic shall not enter into any letter of intent, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement or similar agreement providing for the consummation of a transaction contemplated by any acquisition proposal (other than a confidentiality agreement referred to above entered into in the circumstances referred to above); and
- each of the Tokai board of directors and the Otic board of directors, and each committee thereof, shall not, except as set forth below, adopt, approve or recommend, or publicly propose to adopt, approve or recommend, any acquisition proposal.

Notwithstanding the foregoing or anything to the contrary set forth in the Share Purchase Agreement, at any time prior to the approval of the issuance of Tokai common stock in the Otic Transaction, Tokai's board of directors may effect a recommendation change if:

- Tokai's board of directors shall have determined in good faith (after consultation with outside legal counsel) that the failure to effect a recommendation change could reasonably be expected to be inconsistent with its fiduciary obligations under applicable law;

Table of Contents

- Tokai has provided at least four business days prior written notice to Otic that it intends to effect a recommendation change, including a description in reasonable detail of the reasons for such recommendation change, and written copies of any relevant proposed transactions agreements with any party making a potential superior proposal;
- Tokai has complied in all material respects with the requirements of the Share Purchase Agreement’s “no solicitation” section in connection with any potential superior proposal; and
- if Otic shall have delivered to Tokai a written, binding and irrevocable offer to alter the terms or conditions of the Share Purchase Agreement during the four business day period referred to above, the Tokai board of directors shall have determined in good faith (after consultation with outside legal counsel), after considering the terms of such offer by Otic, that the failure to effect a recommendation change could still reasonably be expected to be inconsistent with its fiduciary obligations under applicable law.

In the event of any material amendment to any superior proposal (including any revision in the amount, form or mix of consideration Tokai’s stockholders would receive as a result of such potential superior proposal), Tokai shall be required to provide Otic with notice of such material amendment and there shall be a new two business day period following such notification during which the parties shall comply again with the requirements of the “recommendation change” section of the Share Purchase Agreement and Tokai’s board of directors shall not make a recommendation change prior to the end of any such period as so extended.

Meeting of Tokai Stockholders

The Share Purchase Agreement requires Tokai to take all actions in accordance with applicable laws, its certificate of incorporation and by-laws and NASDAQ rules to duly call, give notice of, convene and hold as promptly as practicable, after this proxy statement is cleared for mailing by the SEC, the meeting of the holders of Tokai common stock to vote on the issuance of Tokai common stock in the Otic Transaction. Tokai is further required to take all action that is both reasonable and lawful to solicit proxies from its stockholders in favor of the issuance of Tokai common stock in the Otic Transaction.

Covenants; Conduct of the Businesses

Otic agreed that during the period prior to the closing of the Otic Transaction, it will conduct its business in the ordinary course in accordance with past practices and in compliance with all applicable laws, regulations, and certain contracts, pay its debts and taxes and perform other obligations when due (subject to good faith disputes), use commercially reasonable efforts, consistent in all material respects with past practices, to maintain and preserve its and each of its subsidiaries’ business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others have business dealings with it, and to take other agreed-upon actions. Otic also agreed that, subject to certain limited exceptions, without the written consent of Tokai, it will not, during the period prior to closing of the Otic Transaction:

- declare, set aside or pay any dividends on, or make any other distributions in respect of, any of its capital stock; split, combine or reclassify any of its capital stock or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock or any of its other securities; or purchase, redeem or otherwise acquire any shares of its capital stock or any other of its securities or any rights, warrants or options to acquire any such shares or other securities;
- issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any shares of its capital stock, any other voting securities or any securities convertible into or exchangeable for, or any rights, warrants or options to acquire, any such shares, voting securities or convertible or exchangeable securities (other than the issuance of shares of Otic’s ordinary shares upon the exercise of Otic

[Table of Contents](#)

share options or warrants outstanding on the date of the Share Purchase Agreement in accordance with their present terms (including cashless exercises) or Otic share options granted as contemplated by the Share Purchase Agreement;

- amend its certificate of incorporation, by-laws or other comparable charter or organizational documents;
- except for purchases of inventory, raw materials and, to the extent the cost thereof is not in excess of \$100,000 in the aggregate, equipment, in each case in the ordinary course of business, acquire by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or any assets that are material, in the aggregate, to Otic and its subsidiaries, taken as a whole;
- except in the ordinary course of business, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets of Otic or of any of its subsidiaries;
- whether or not in the ordinary course of business, sell, dispose of or otherwise transfer any assets material to Otic and its subsidiaries, taken as a whole (including any accounts, leases, contracts or intellectual property or any assets or the stock of any of its subsidiaries, but excluding the sale or license of products in the ordinary course of business);
- incur or suffer to exist any indebtedness for borrowed money other than such indebtedness that existed as of September 30, 2016 to the extent disclosed to Tokai or guarantee any such indebtedness of another person, provided, however, that if the closing does not occur on or prior to March 1, 2017, Otic shall have the right, in its sole discretion, to incur up to an aggregate of \$3,000,000 of additional indebtedness from the Sellers on the terms disclosed to Tokai, issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Otic or any of its subsidiaries, guarantee any debt securities of another person, enter into any “keep well” or other agreement to maintain any financial statement condition of another person or enter into any arrangement having the economic effect of any of the foregoing, make any loans, advances (other than routine advances to employees of Otic in the ordinary course of business) or capital contributions to, or investment in, any other person, other than Otic or any of its direct or indirect wholly owned subsidiaries or enter into any hedging agreement or other financial agreement or arrangement designed to protect Otic or its subsidiaries against fluctuations in commodities prices or exchange rates;
- make any capital expenditures or other expenditures with respect to property, plant or equipment, other than as set forth in Otic’s budget for capital expenditures previously made available to Tokai or the specific capital expenditures disclosed to Tokai;
- make any changes in accounting methods, principles or practices, except insofar as may have been required by a change in GAAP or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;
- except in the ordinary course of business or for terminations as a result of the expiration of any contract that expires in accordance with terms, modify or amend in any material respect, or terminate, any material contract or agreement to which Otic or any of its subsidiaries is party; or knowingly waive, release or assign any material rights or claims (including any write-off or other compromise of any accounts receivable of Otic or any of its subsidiaries);
- except in the ordinary course of business, enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products, of, or products licensed by, Otic or any of its subsidiaries or license any material intellectual property rights to or from any third party;
- except as required to comply with applicable law or agreements, plans or arrangements existing on the date of the Share Purchase Agreement and either disclosed to Tokai or not required by the Share

[Table of Contents](#)

Purchase Agreement to be disclosed, take any action with respect to any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, increase in any material respect the compensation or fringe benefits of, or pay any material bonus to, any director, officer, employee or consultant, amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding options or restricted stock awards, pay any material benefit not provided for as of the date of the Share Purchase Agreement under any benefit plan, grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan, or take any action other than in the ordinary course of business to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

- make or change any material tax election, change an annual accounting period, enter into any closing agreement, waive or extend any statute of limitations with respect to taxes, settle or compromise any material tax liability, claim or assessment, surrender any right to claim a refund of material taxes, or amend any income or other material tax return;
- commence any offering of shares of Otic ordinary shares pursuant to any Employee Stock Purchase Plan;
- initiate, compromise or settle any material litigation or arbitration proceeding;
- open or close any facility or office;
- fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of the Share Purchase Agreement;
- fail to pay accounts payable and other obligations in the ordinary course of business;
- suspend any clinical trials sponsored by Otic or involving any products marketed or in development by Otic;
- permit the exercise of any Otic share options or Otic warrants by any person who is not a signatory to the Share Purchase Agreement, unless such person first executes a joinder agreement agreeing to be bound by the terms of the Share Purchase Agreement in form and substance reasonable acceptable to Tokai; or
- authorize any of, or commit or agree, in writing or otherwise, to take any of, the foregoing actions or any action that would make any representation or warranty of Otic in the Share Purchase Agreement untrue or incorrect in any material respect, or would materially impair or prevent the satisfaction of conditions in the Share Purchase Agreement.

Tokai agreed that during the period prior to the closing of the Otic Transaction, it will conduct its business in the ordinary course in accordance with past practices and in compliance with all applicable laws, regulations, and certain contracts, pay its debts and taxes and perform other obligations when due (subject to good faith disputes), use commercially reasonable efforts, consistent in all material respects with past practices, to maintain and preserve its and each of its subsidiaries' business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others have business dealings with it, and to take other agreed-upon actions. Tokai also agreed that, subject to certain limited exceptions, without the written consent of Otic, it will not, during the period prior to closing of the Otic Transaction:

- split, combine or reclassify any of its capital stock or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock or any of its other securities; or purchase, redeem or otherwise acquire any shares of its capital stock or any other of its securities or any rights, warrants or options to acquire any such shares or other securities;

[Table of Contents](#)

- issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any shares of its capital stock, any other voting securities or any securities convertible into or exchangeable for, or any rights, warrants or options to acquire, any such shares, voting securities or convertible or exchangeable securities (in each case other than the issuance of shares of Tokai common stock upon the exercise of Tokai options or warrants outstanding on the date of the Share Purchase Agreement in accordance with their present terms (including cashless exercises));
- amend its certificate of incorporation, by-laws or other comparable charter or organizational documents;
- except for purchases of inventory and raw materials in the ordinary course of business, acquire by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or any assets that are material, in the aggregate, to Tokai and its subsidiaries, taken as a whole;
- except in the ordinary course of business, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets of Tokai or of any of its subsidiaries;
- whether or not in the ordinary course of business, sell, dispose of or otherwise transfer any assets material to Tokai and its subsidiaries, taken as a whole (including any accounts, leases, contracts or intellectual property or any assets or the stock of any of its subsidiaries, but excluding the sale or license of products in the ordinary course of business);
- incur or suffer to exist any indebtedness for borrowed money or guarantee any such indebtedness of another person, issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Tokai or any of its subsidiaries, guarantee any debt securities of another person, enter into any “keep well” or other agreement to maintain any financial statement condition of another person or enter into any arrangement having the economic effect of any of the foregoing, make any loans, advances (other than routine advances to employees of Tokai in the ordinary course of business) or capital contributions to, or investment in, any other person, other than Tokai or any of its direct or indirect wholly owned subsidiaries or enter into any hedging agreement or other financial agreement or arrangement designed to protect Tokai or its subsidiaries against fluctuations in commodities prices or exchange rates;
- make any capital expenditures or other expenditures, other than those contemplated by the Tokai financial model provided to Otic on the date of the Share Purchase Agreement; provided that variances in any line item in the financial model shall be permitted to the extent the aggregate expenditures do not exceed the amount shown in the model (except as follows), additional expenditures not exceeding 10% of the amount of aggregate expenditures shown in the model and expenditures incurred by the Tokai as a result of events or circumstances involving the Tokai’s ongoing clinical trials that arise outside of the Tokai’s control;
- make any changes in accounting methods, principles or practices, except insofar as may have been required by the SEC or a change in GAAP or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;
- except in the ordinary course of business or for terminations as a result of the expiration of any contract that expires in accordance with its terms, modify or amend in any material respect, or terminate, any material contract or agreement to which Tokai or any of its subsidiaries is party, or knowingly waive, release or assign any material rights or claims;
- except in the ordinary course of business, enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products, of, or products licensed by, Tokai or any of its subsidiaries or license any material intellectual property rights to or from any third party;

Table of Contents

- except as required to comply with applicable law or agreements, plans or arrangements existing on the date of the Share Purchase Agreement and either disclosed to Otic, not required by the Share Purchase Agreement to be so disclosed or disclosed in Tokai's SEC filings or furnished prior to the date of the Share Purchase Agreement, take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, increase in any material respect the compensation or fringe benefits of, or pay any material bonus to, any director, officer, employee or consultant, amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding options or restricted stock awards, pay any material benefit not provided for as of the date of the Share Purchase Agreement under any benefit plan, grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan, hire any additional officers or other employees, or any consultants or independent contractors, in each case, other than as disclosed to Otic and employees, consultants or independent contractors hired to fill open position created as a result of the separation of service of an officer, employee, consultant or independent contractor, as applicable, after the date of the Share Purchase Agreement, or take any action other than in the ordinary course of business to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;
- make or change any material tax election, change an annual accounting period, enter into any closing agreement, waive or extend any statute of limitations with respect to taxes, settle or compromise any material tax liability, claim or assessment, surrender any right to claim a refund of material taxes, or amend any income or other material tax return;
- commence any offering of shares of Tokai's common stock pursuant to any Employee Stock Purchase Plan;
- open or close any facility or office;
- initiate, compromise or settle any material litigation or arbitration proceeding;
- fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of the Share Purchase Agreement;
- fail to pay accounts payable and other obligations in the ordinary course of business; or
- authorize any of, or commit or agree, in writing or otherwise, to take any of, the foregoing actions or any action that would make any representation or warranty of Tokai in the Share Purchase Agreement untrue or incorrect in any material respect, or would materially impair or prevent the satisfaction of conditions in the Share Purchase Agreement.

Indemnification and Insurance

Pursuant to the Share Purchase Agreement, Tokai, Otic and the Sellers agreed that, from the closing of the Otic Transaction through the sixth anniversary of the closing, Tokai will indemnify and hold harmless each person who as of the date of the Share Purchase Agreement is, or who becomes prior to the closing, or has been at any time prior to the consummation of the Otic Transaction, a director or officer of Tokai or Otic or any of their respective subsidiaries against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that such director or officer is or was an officer or director of Otic, Tokai or any of their respective subsidiaries, whether asserted or claimed prior to, at or after the closing, to the fullest extent permitted by applicable law. Each such director or officer will be entitled to advancement of expenses (including attorneys' fees) incurred in the defense of any such claim, action, suit, proceeding or investigation from Tokai following

[Table of Contents](#)

receipt by Tokai from the director or officer of a request therefor; provided that any person to whom expenses are advanced provides an undertaking, to the extent then required by the DGCL, to repay such advances if it is ultimately determined that such person is not entitled to indemnification. The certificate of incorporation and by-laws of Tokai will contain provisions at least as favorable as the provisions relating to the indemnification, advance of expenses and elimination of liability for monetary damages set forth in the certificate of incorporation and by-laws of Tokai on the date of the Share Purchase Agreement.

Tokai shall either maintain in effect for six years after the closing of the Otic Transaction Tokai's existing directors' and officers' insurance policies in place as of the date of the Share Purchase Agreement, or prior to the closing, purchase a six-year "tail" policy under its own existing directors' and officers' liability insurance policy, with an effective date as of the closing (provided that Tokai may substitute therefor a policy of at least the same coverage containing terms and conditions that are not less favorable in any material respect); provided, however, that in no event shall Tokai be required to expend pursuant to this section of the Share Purchase Agreement more than an amount equal to 200% of the current annual premiums paid by Tokai for such insurance; provided, further, that during the term of the "tail" policy, Tokai shall not take any action following the closing to cause such "tail" policy to be cancelled or any provision therein to be amended or waived in any manner that would adversely affect in any material respect the rights of their former and current officers and directors.

Tokai shall pay all expenses, including reasonable attorneys' fees, that may be incurred by a person in successfully enforcing such person's rights provided in this section of the Share Purchase Agreement.

Tokai and Otic agree that all rights to exculpation, indemnification and advancement of expenses for acts or omissions occurring at or prior to the closing, whether asserted or claimed prior to, at or after the closing, now existing in favor of the current or former directors, officers or employees, as the case may be, of Tokai, Otic or any of their respective subsidiaries as provided in their respective certificates of incorporation or by-laws or other organization documents or in any agreement shall survive the Otic Transaction and shall continue in full force and effect. The provisions of this section of the Share Purchase Agreement are intended to be in addition to the rights otherwise available to the current officers and directors of Tokai, Otic or any of their respective subsidiaries by law, charter, statute, by-law or agreement, and shall operate for the benefit of, and shall be enforceable by, each of the officers or directors, their heirs and their representatives. The obligations set forth in this section of the Share Purchase Agreement shall not be terminated, amended or otherwise modified in any manner that adversely affects any officer or director, or any person who is a beneficiary under the policies referred to in this section of the Share Purchase Agreement and their heirs and representatives, without the prior written consent of such affected director or officer or other person.

If Tokai, Otic or any of their respective successors or assigns shall (i) consolidate with or merge into any other person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfer all or substantially all of its properties and assets to any person, then, and in each such case, proper provisions shall be made so that the successors and assigns of such person shall assume all of the indemnification and insurance obligations of such person set forth in this section of the Share Purchase Agreement.

Other Agreements

Tokai and Otic have additionally agreed to use commercially reasonable efforts to take, or cause to be taken, all actions, and do, or cause to be done, and to assist and cooperate with the other parties in doing, all things necessary, proper or advisable to consummate and make effective the transactions contemplated by the Share Purchase Agreement, and to:

- use commercially reasonable efforts to obtain, as promptly as practicable, each consent, if any, required to be obtained pursuant to any applicable law, any of Otic's material contracts, or otherwise, by such party in connection with any of the transactions contemplated by the Share Purchase Agreement or in order for any of Otic's material contracts to remain in full force and effect;

Table of Contents

- give all notices, if any, and use commercially reasonable efforts to make all necessary filings and other submissions required to be made and given in connection with the transactions contemplated by the Share Purchase Agreement, if any, as promptly as practicable; and
- use commercially reasonable efforts to execute or deliver any additional instruments necessary to consummate the transactions contemplated by, and to fully carry out the purposes of, the Share Purchase Agreement.

In addition, Tokai, Otic and the Sellers have agreed that:

- Tokai will use its commercially reasonable efforts to continue its existing listing on NASDAQ and to cause the shares of Tokai common stock being issued in the Otic Transaction to be approved for listing, subject to notice of issuance, on NASDAQ at or prior to the closing of the Otic Transaction;
- Tokai will take all action necessary to reconstitute the Tokai board of directors and appoint executive officers pursuant to the terms of the Share Purchase Agreement, including appointing the individuals identified in the section entitled “*Terms of the Share Purchase Agreement—Directors and Officers of Tokai Following the Otic Transaction,*” beginning on page 99 of this proxy statement;
- promptly after the closing, Tokai shall take all action necessary to cause its certificate of incorporation to be amended to reflect a change in Tokai’s name to OticPharma, Inc.; and
- Tokai and Otic will use reasonable efforts to consult with each other, and will consider in good faith each other’s advice, prior to sending any notices or other communication materials to such party’s employees regarding the Share Purchase Agreement, the Otic Transaction or its effects on the employment, compensation or benefits of its employees.

Lock-up Agreements

Pursuant to the Share Purchase Agreement, each of the Sellers agreed not to, except in limited circumstances, sell or transfer, or engage in swap or similar transactions with respect to, any shares of Tokai common stock or any securities exercisable or exchangeable for Tokai common stock including, as applicable, shares and other securities received in the transaction from the closing of the Otic Transaction until 180 days following the closing of the Otic Transaction.

Termination of the Share Purchase Agreement

The Share Purchase Agreement may be terminated before the consummation of the Otic Transaction, whether before or after the required stockholder approvals to complete the Otic Transaction have been obtained, as set forth below:

- by mutual written consent of Tokai and Otic;
- by either Tokai or Otic, if the Otic Transaction has not been consummated by April 30, 2017 (the “*Outside Date*”); provided, however, that this right to terminate the Share Purchase Agreement will not be available to a party if such party’s failure to fulfill any obligation under the Share Purchase Agreement has been a principal cause of or resulted in the failure of the Otic Transaction to occur on or before the Outside Date;
- by Tokai or Otic, if a court of competent jurisdiction or governmental entity has issued a final and nonappealable order, decree or ruling or taken any other action that permanently restrains, enjoins or otherwise prohibits the Otic Transaction; provided, that this right to terminate will not be available to a party if the issuance of such order, decree, ruling or other action is attributable to the failure of such party (or any affiliate of such party) to perform in any material respect any covenant in the Share Purchase Agreement required to be performed by such party (or any affiliate of such party) at or prior to closing;

Table of Contents

- by Tokai, if Otic has knowingly and materially breached its non-solicitation obligations in the Share Purchase Agreement;
- by Otic, if at any time prior to the approval by Tokai's stockholders of the issuance of the shares of Tokai common stock in the Otic Transaction, Tokai's board of directors fails to recommend that the stockholders of Tokai vote to approve the issuance of Tokai common stock or withdraws or modifies its recommendation, Tokai's board of directors (or any committee thereof) approves or recommends to the Tokai stockholders an acquisition proposal, a tender or exchange offer for outstanding shares of Tokai's common stock is commenced and Tokai's board of directors recommends that the Tokai stockholders tender or exchange their shares in such offer or Tokai's board of directors fails to recommend against such offer within ten business days of its commencement, or Tokai has knowingly and materially breached its no solicitation obligations in to the Share Purchase Agreement;
- by Tokai, if there has been a material breach of or failure to perform any representation, warranty, covenant or agreement set forth in the Share Purchase Agreement on the part of Otic, which breach would cause a closing condition in the Share Purchase Agreement not to be satisfied; provided that Tokai is not then in material breach of the Share Purchase Agreement; and provided further, that if such breach or failure to perform is curable by Otic, then the Share Purchase Agreement shall not terminate as a result of such breach or failure until the earlier of the Outside Date or the expiration of a 30-day period commencing upon delivery of written notice from Tokai to Otic of such breach, it being understood that the Share Purchase Agreement shall not so terminate if such breach or violation is cured prior to termination becoming effective;
- by Otic, if there has been a material breach of or failure to perform any representation, warranty, covenant or agreement set forth in the Share Purchase Agreement on the part of Tokai, which breach would cause a closing condition in the Share Purchase Agreement not to be satisfied; provided that Otic is not then in material breach of the Share Purchase Agreement; and provided further, that if such breach or failure to perform is curable by Tokai, then the Share Purchase Agreement shall not terminate as a result of such breach or failure until the earlier of the Outside Date or the expiration of a 30-day period commencing upon delivery of written notice from Otic to Tokai of such breach, it being understood that the Share Purchase Agreement shall not so terminate if such breach or violation is cured prior to termination becoming effective; or
- by Tokai, if at any time prior to the approval by Tokai's stockholders of the issuance of the shares of Tokai common stock in the Otic Transaction, each of the following occur: Tokai receives a superior proposal (as such term is defined in the section entitled, "*Terms of the Share Purchase Agreement—No Solicitation; Third Party Competing Proposa*") in this proxy statement beginning on page 101); Tokai has complied in all material respects with its non-solicitation obligations in the Share Purchase Agreement in order to accept such superior proposal; the Tokai Board of Directors approves, and Tokai concurrently with termination of the Share Purchase Agreement enters into, a definitive agreement with respect to such superior proposal; and prior to or concurrently with such termination, Tokai pays to Otic the "*Tokai termination fee*" (as defined below).

In the event that Tokai or Otic terminates the Share Purchase Agreement before the Otic Transaction is consummated, the Share Purchase Agreement will be of no further force or effect, except the Share Purchase Agreement's provisions regarding termination fees and certain other miscellaneous provisions specified in the Share Purchase Agreement, as well as the confidentiality agreement between Tokai and Otic, shall remain in full effect. However, terminating the Share Purchase Agreement cannot relieve from liability any party to the Share Purchase Agreement for any knowing and intentional breach of the Share Purchase Agreement.

Termination Fee and Expenses

Except as otherwise set forth in the Share Purchase Agreement, all fees and expenses incurred in connection with the Share Purchase Agreement are to be paid by the party incurring such expenses, regardless of whether the Otic Transaction is consummated.

However, Otic must pay Tokai a termination fee of \$1.5 million if:

- Tokai has terminated the Share Purchase Agreement as a result of a knowing and material breach by Otic of its non-solicitation obligations in the Share Purchase Agreement; or
- Tokai has terminated the Share Purchase Agreement as a result of a material breach or failure to perform by Otic of any representation, warranty, covenant or agreement set forth in the Share Purchase Agreement, which breach has caused a closing condition in the Share Purchase Agreement not to be satisfied; provided that Tokai was not then in material breach of the Share Purchase Agreement; and provided further, that such breach or failure to perform was not been cured by Otic, as applicable, prior to the earlier of the Outside Date and the expiration of a 30-day period commencing upon delivery of written notice from Tokai to Otic of such breach.

Tokai must pay Otic a termination fee of \$1.0 million (the “*Tokai termination fee*”) if:

- Tokai has terminated the Share Purchase Agreement at any time prior to the approval by Tokai’s stockholders of the issuance of the shares of Tokai common stock in the Otic Transaction and each of the following has occurred: Tokai receives a superior proposal (as such term is defined in the section entitled, “*Terms of the Share Purchase Agreement—No Solicitation; Third Party Competing Proposal*” in this proxy statement beginning on page 101); Tokai has complied in all material respects with its non-solicitation obligations in the Share Purchase Agreement in order to accept such superior proposal; the Tokai Board of Directors approves, and Tokai concurrently with termination of the Share Purchase Agreement enters into, a definitive agreement with respect to such superior proposal;
- so long as prior to the termination of the Share Purchase Agreement, any person makes an acquisition proposal or amends an acquisition proposal made prior to the date of the Share Purchase Agreement with respect to Tokai and within 12 months after such termination Tokai enters into a definitive agreement to consummate, or consummates, any acquisition proposal (provided that for purposes of this termination section, references to 15% in the definition of “acquisition proposal” shall be deemed to be 50%) and:
 - either Otic or Tokai has terminated the Share Purchase Agreement and the Otic Transaction has not been consummated prior to the outside date; provided, such terminating party did not cause such failure to fulfill any obligation under the Share Purchase Agreement and was not a principal cause of or resulted in the failure of the Otic Transaction to so occur prior to the outside date; or
 - Otic has terminated the Share Purchase Agreement as a result of a material breach or failure to perform by Tokai of any representation, warranty, covenant or agreement set forth in the Share Purchase Agreement, which breach has caused a closing condition in the Share Purchase Agreement not to be satisfied; provided that Otic was not then in material breach of the Share Purchase Agreement; and provided further, that such breach or failure to perform was not been cured by Otic, as applicable, prior to the earlier of the Outside Date and the expiration of a 30-day period commencing upon delivery of written notice from Otic to Tokai of such breach; or
- Otic has terminated the Share Purchase Agreement at any time prior to the approval by Tokai’s stockholders of the issuance of the shares of Tokai common stock in the Otic Transaction due to the occurrence of any of the following: Tokai’s board of directors failed to recommend that the stockholders of Tokai vote to approve the issuance of Tokai common stock in the Otic Transaction

[Table of Contents](#)

or withdrew or modified its recommendation, Tokai's board of directors (or any committee thereof) approved or recommended to the Tokai stockholders an acquisition proposal, a tender or exchange offer for outstanding shares of Tokai's common stock was commenced and Tokai's board of directors recommended that the Tokai stockholders tender or exchange their shares in such offer or Tokai's board of directors failed to recommend against such offer within ten business days of its commencement, or Tokai has knowingly and materially breached its no solicitation obligations in to the Share Purchase Agreement.

Otic, the Sellers and Tokai agreed that the termination fee and expense reimbursements described in this section of this proxy statement are the sole and exclusive remedy of Tokai and Otic, as applicable in connection with the termination of the Share Purchase Agreement.

Regulatory Approvals

Neither Tokai nor Otic is required to make any filings or to obtain approvals or clearances from any regulatory authorities in the United States or other countries to consummate the Otic Transaction contemplated by the Share Purchase Agreement. In Israel, Otic is required to prepare, file and receive all Israeli tax rulings with respect to the Otic Transaction, and Tokai is required to deliver to Otic an executed copy of an undertaking in the standard form required by the Office of the Chief Scientist from non-Israeli residents investing in Israeli companies which have received support from the OCS. In the United States, Tokai must comply with applicable federal and state securities laws and NASDAQ rules and regulations in connection with the issuance of shares of Tokai common stock in the Otic Transaction and the issuance of shares of Tokai common stock in the Equity Financing, including the filing with the SEC of this proxy statement.

Pursuant to the terms of the Share Purchase Agreement, Tokai and Otic must use commercially reasonable efforts to file or otherwise submit, as promptly as practicable after the date of the Share Purchase Agreement, all necessary filings with respect to the transactions contemplated by the Share Purchase Agreement, to make any required submissions, and to execute or deliver any additional instruments necessary to consummate the transactions contemplated by, and to fully carry out the purposes of, the Share Purchase Agreement.

Amendments and Waivers

The Share Purchase Agreement may be amended by the parties by action taken or authorized by their respective boards of directors, and with respect to the Sellers, by action taken by the Sellers holding a majority of the issued and outstanding Otic share capital, at any time before or after approval by the Tokai stockholders of the issuance of Tokai common stock in the transaction, but after such approval, no amendment shall be made which by law requires further approval by such stockholders without such further approval. All amendments of the Share Purchase Agreement require an instrument in writing signed on behalf of each of Tokai, Otic, and the Sellers holding a majority of the issued and outstanding Otic share capital.

Any agreement on the part of a party to the Share Purchase Agreement to extension or waiver is valid only if set forth in a written instrument signed on behalf of such party. The failure of any party to the Share Purchase Agreement to assert any of its rights under the Share Purchase Agreement shall not constitute a waiver of such rights.

Specific Performance

Tokai, Otic and the Sellers agreed that irreparable damage would occur in the event that any of the provisions of the Share Purchase Agreement were not performed in accordance with their specific terms or were otherwise breached. Accordingly, Tokai, Otic or any Seller, as the case may be, is entitled to an injunction or injunctions to prevent breaches of the Share Purchase Agreement and to enforce specifically the terms and provisions thereof, this being in addition to any other remedy to which such party is entitled at law or in equity.

[Table of Contents](#)

Third Party Beneficiaries

Nothing in the Share Purchase Agreement confers upon any other person, other than Tokai, Otic and the Sellers, and to a limited extent related to indemnification, certain directors and officers of Tokai and Otic, any right, benefit or remedy of any nature whatsoever under or by reason of the Share Purchase Agreement.

**AGREEMENTS RELATED TO THE SHARE
PURCHASE AGREEMENT**

Support Agreement

As a condition and inducement to, and in consideration for, Otic's and the Sellers' willingness to enter into the Share Purchase Agreement, certain stockholders, directors and officers of Tokai entered into a Support Agreement with Otic pursuant to which, among other things, each of these equityholders agreed, solely in its capacity as an equityholder, to vote all of its shares of Tokai common stock in favor of the issuance of Tokai common stock in the Otic Transaction and against any "acquisition proposal," as defined in the Share Purchase Agreement and described in the section entitled, "*Terms of the Share Purchase Agreement—No Solicitation; Third Party Competing Proposal*," beginning on page 101 of this proxy statement.

The parties to the Support Agreement with Otic are: Apple Tree Partners II, L.P., Apple Tree Partners II—Annex, L.P., Apple Tree Partners IV, L.P., Jodie P. Morrison, Seth L. Harrison, M.D., Stephen Buckley, Jr., Cheryl L. Cohen, David A. Kessler, M.D., and Joseph A. Yanchik, III.

The Tokai equityholders that are party to the Support Agreement, as of December 31, 2016, beneficially owned an aggregate of 8,218,885 shares of Tokai common stock, representing approximately 36.3% of the outstanding common stock of Tokai.

Under the Support Agreement, subject to certain exceptions, such Tokai equityholders also have agreed not to sell or transfer Tokai shares and/or options, as applicable, held by them, or any voting rights with respect thereto, until the earlier of the termination of the Share Purchase Agreement or the consummation of the Otic Transaction. To the extent that any such sale or transfer is permitted pursuant to the exceptions included in the Support Agreement, each person to which any shares of Tokai shares and/or options, as applicable, are so sold or transferred must agree in writing to be bound by the terms and provisions of the Support Agreement.

Tokai Stock Purchase Agreement

In connection with the Otic Transaction, Tokai has entered into the Tokai Stock Purchase Agreement dated January 10, 2017 with Otic and certain purchasers set forth therein pursuant to which the purchasers have agreed to purchase 1,000,000 shares of Tokai common stock at a price of \$1.11 per share. The Tokai Stock Purchase Agreement provides that the purchase and sale of the Tokai common stock will occur immediately following the closing of the Otic Transaction.

The issuance of shares pursuant to the Tokai Stock Purchase Agreement is subject to certain closing conditions, including:

- the closing of the Otic Transaction;
- accuracy of representations and warranties, subject to customary materiality standards;
- performance of covenants in all material respects;
- execution of a registration rights agreement, further described below;
- delivery of a legal opinion to the purchasers; and
- filing of a listing of additional shares with NASDAQ, and if required, stockholder approval for the issuance of common stock pursuant to the Tokai Stock Purchase Agreement.

Registration Rights Agreement

Pursuant to the Tokai Stock Purchase Agreement, Tokai and the purchasers set forth therein have also agreed to enter into a registration rights agreement, under which Tokai will agree to register the shares issued pursuant to the Tokai Stock Purchase Agreement (the "*registrable securities*") under the Securities Act as

[Table of Contents](#)

described below and will have incidental registration rights as described below. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act.

Required registration

On or prior to the 45th day following the closing of the Tokai Stock Purchase Agreement (the “*filing date*”), Tokai will prepare and file a registration statement on Form S-3 (except if Tokai is not then eligible to register for resale the registrable securities on Form S-3, in which case such registration shall be on another appropriate form in accordance to cover all the registrable securities not then registered). Tokai has agreed to use its commercially reasonable efforts to cause such registration statement to be declared effective under the Securities Act promptly but, in any event, no later than the 120th day following the closing date of the Tokai Stock Purchase Agreement (or the 150th day following the closing date under the Tokai Stock Purchase Agreement in the event the registration statement is reviewed by the Securities and Exchange Commission) (the “*effectiveness deadline*”), and shall, subject to the limitations described below, use its commercially reasonable efforts to keep the registration statement continuously effective under the Securities Act until the earlier of (i) the date that is three years after the closing date of the Tokai Stock Purchase Agreement and (ii) the date on which all securities under such registration statement have ceased to be registrable securities. Notwithstanding the foregoing, Tokai shall be entitled to suspend the effectiveness of the registration statement at any time prior for up to an aggregate of 30 consecutive trading days or an aggregate of 60 trading days (which need not be consecutive) in any given 360-day period.

If for any reason the Securities and Exchange Commission limits the number of shares of common stock allowed for inclusion in a registration statement, Tokai shall file additional registration statements subject to the same terms described above until all registrable securities are included in registration statements.

If the registration statement is not filed by the filing date, effective by the effectiveness deadline or ceases to be effective other than pursuant to the exemptions described above, then in addition to any other rights the purchasers may have hereunder or under applicable law, on each such date and on each monthly anniversary of each such date (if not cured by such date) until the earlier of (1) the applicable event is cured or (2) the registrable securities are eligible for resale pursuant to Rule 144 without manner of sale or volume restrictions or the current public information requirement, Tokai shall pay to each purchaser an amount in cash, as liquidated damages and not as a penalty, equal to 1% of the aggregate purchase price paid by such purchaser pursuant to the Tokai Stock Purchase Agreement.

Expenses

Tokai has agreed to pay all registration expenses, including registration fees, printing expenses, fees and disbursements of our counsel and accountants and reasonable fees and disbursements of one counsel representing any selling stockholders, other than any underwriting discounts and commissions, related to any demand or incidental registration. The registration rights agreement will contain customary cross-indemnification provisions, pursuant to which Tokai is obligated to indemnify any purchaser in the event of material misstatements or omissions in the registration statement attributable to Tokai, and each purchaser is obligated to indemnify Tokai for material misstatements or omissions in the registration statement attributable to it.

SHARE ISSUANCES PROPOSAL

APPROVAL OF THE ISSUANCE OF TOKAI COMMON STOCK PURSUANT TO THE SHARE PURCHASE AGREEMENT AND THE TOKAI STOCK PURCHASE AGREEMENT

At the special meeting, Tokai stockholders will be asked to approve the issuance of Tokai common stock in the Otic Transaction pursuant to the Share Purchase Agreement and the related issuance of Tokai common stock pursuant to the Tokai Stock Purchase Agreement. The number of shares of Tokai common stock to be issued to the Sellers in the Otic Transaction will be determined pursuant to the exchange ratio set forth in the Share Purchase Agreement and in the section entitled “*Terms of the Share Purchase Agreement—Exchange Ratio*,” beginning on page 98 of this proxy statement.

The terms of, reasons for and other aspects of the Share Purchase Agreement and the issuance of Tokai common stock in the Otic Transaction as well as the terms of, reasons for and other aspects of the Tokai Stock Purchase Agreement and the issuance of Tokai common stock in the Equity Financing are described in detail in the other sections in this proxy statement.

Presuming a quorum is present, approval of the Share Issuances Proposal requires the affirmative vote of a majority of the shares of Tokai common stock, present in person or represented by proxy and entitled to vote on the subject matter (excluding broker non-votes and abstentions).

THE TOKAI BOARD OF DIRECTORS RECOMMENDS THAT THE TOKAI STOCKHOLDERS VOTE “FOR” THE SHARE ISSUANCES PROPOSAL TO APPROVE THE ISSUANCES OF TOKAI COMMON STOCK PURSUANT TO THE TERMS OF THE SHARE PURCHASE AGREEMENT AND PURSUANT TO THE TOKAI STOCK PURCHASE AGREEMENT. EACH OF THE SHARE ISSUANCES PROPOSAL, THE REVERSE STOCK SPLIT PROPOSAL AND THE ADJOURNMENT PROPOSAL IS AN INDEPENDENT PROPOSAL; NONE OF THE FOREGOING IS CONDITIONED UPON ANOTHER PROPOSAL. THE APPROVAL OF THE SHARE ISSUANCES PROPOSAL IS REQUIRED TO CONSUMMATE THE OTIC TRANSACTION. THE OTIC TRANSACTION MAY BE CONSUMMATED REGARDLESS OF WHETHER THE TOKAI STOCKHOLDERS APPROVE OR DO NOT APPROVE THE REVERSE STOCK SPLIT PROPOSAL OR THE ADJOURNMENT PROPOSAL.

REVERSE STOCK SPLIT PROPOSAL

APPROVAL OF CHARTER AMENDMENT TO EFFECT THE REVERSE STOCK SPLIT

Pursuant to the Share Purchase Agreement, Tokai agreed to seek stockholder approval for a reverse stock split with the specific terms to be proposed by Tokai and approved by Otic to the extent necessary in order to maintain Tokai's listing on NASDAQ. Based on information currently available to Tokai, Tokai anticipates that it will be unable to meet the \$4.00 minimum bid price initial listing requirement at the closing of the Otic Transaction unless it effects a reverse stock split. Therefore, the Tokai board of directors has approved a proposed amendment to the Amended and Restated Certificate of Incorporation of Tokai to effect a reverse stock split of all issued and outstanding shares of Tokai common stock, at a ratio of one new share for a number of outstanding shares between and including _____ and _____, such number to be determined by the Tokai board of directors and agreed to by Otic.

If the reverse stock split proposal is approved and subject to Tokai's obligations under the Share Purchase Agreement to consult with Otic, the Tokai board of directors will have the sole discretion, but not the obligation, at any time within _____ months of the date of the special meeting and in accordance with Section 242(c) of the DGCL to elect, as it determines to be in the best interests of Tokai and its stockholders, whether to effect a reverse stock split, and if so, the number of shares of Tokai common stock between and including _____ and _____ that will be combined and reclassified into one share of Tokai common stock. The Tokai board of directors believes that the reverse stock split proposal provides the Tokai board of directors with maximum flexibility to react to market conditions and, therefore, is in the best interests of Tokai and its stockholders.

If the reverse stock split proposal is approved and the Tokai board of directors determines that effecting a reverse stock split is in the best interests of Tokai and its stockholders, the reverse stock split will become effective upon the filing of the proposed amendment with the Secretary of State of the State of Delaware, which filing will contain the number of shares determined by the Tokai board of directors subject to the limits discussed above to be combined and reclassified into one share of Tokai common stock. The Tokai board of directors' decision to effect a reverse stock split, and its determination of the reverse stock split ratio, will be based on a number of factors, including market conditions, existing and expected trading prices for Tokai common stock and the applicable listing requirements of The NASDAQ Global Market.

If the Share Issuances Proposal and Reverse Stock Split Proposal are approved by Tokai stockholders, the Tokai board of directors, with agreement of Otic, expects to effect the reverse stock split through the filing of an amendment to the Amended and Restated Certificate of Incorporation prior to the closing of the Otic Transaction. The exact number of shares to be issued in the Otic Transaction and in the Equity Financing and the exact exchange ratio discussed in this proxy statement do not reflect this reverse stock split.

Upon the effectiveness of the proposed amendment effecting the reverse stock split, or the reverse split effective time, the shares of Tokai common stock outstanding immediately prior to the reverse split effective time will be combined and reclassified into a smaller number of shares such that a Tokai stockholder will own one new share of Tokai common stock for such number of shares, as determined by the Tokai board of directors and agreed to by Otic, of Tokai common stock held by such stockholder immediately prior to the reverse split effective time. The actions taken in connection with the reverse stock split will reduce the number of outstanding shares of Tokai common stock.

Additionally, pursuant to the various instruments governing Tokai's then outstanding stock awards, in connection with any reverse stock split, Tokai's Board of Directors will reduce the number of shares of common stock issuable upon the exercise of such stock awards in proportion to the ratio of the reverse stock split and proportionately increase the exercise price of Tokai's outstanding stock options. In connection with such proportionate adjustments, the number of shares of common stock issuable upon exercise or conversion of outstanding stock awards will be rounded down to the nearest whole share and the exercise prices will be rounded up to the nearest cent, and no cash payment will be made in respect of such rounding.

[Table of Contents](#)

The form of the amendment to the Amended and Restated Certificate of Incorporation of Tokai to effect the reverse stock split, as more fully described below, will not change the number of authorized shares of common stock or preferred stock, or the par value of Tokai common stock or preferred stock.

Purpose

The Tokai board of directors approved the proposal approving the amendment to the Amended and Restated Certificate of Incorporation of Tokai effecting the reverse stock split for the following reasons:

- under the Share Purchase Agreement, Tokai agreed to seek stockholder approval for a reverse stock split at a ratio mutually agreed to by Tokai and Otic if necessary in order to maintain the listing of Tokai's common stock on NASDAQ;
- the Tokai board of directors believes effecting the reverse stock split may be an effective means of maintaining the compliance of Tokai common stock with the listing requirements of The NASDAQ Global Market in the future;
- the Tokai board of directors believes a higher stock price may help generate investor interest in Tokai and help Tokai attract and retain employees; and
- if the reverse stock split successfully increases the per share price of Tokai common stock, the Tokai board of directors believes this increase may increase trading volume in Tokai common stock and facilitate future financings by Tokai.

NASDAQ Listing Requirements

Tokai common stock is currently quoted on The NASDAQ Global Market under the symbol "TKAI". Tokai, in coordination with Otic, intends to file an initial listing application with NASDAQ to seek listing on The NASDAQ Global Market upon the closing of the Otic Transaction and expects to trade on The NASDAQ Global Market under the symbol "AOME."

According to NASDAQ rules, an issuer must, in a case such as this, apply for initial inclusion following a transaction whereby the issuer combines with a non-NASDAQ entity, resulting in a change in control of the issuer and potentially allowing the non-NASDAQ entity to obtain a NASDAQ listing. Accordingly, the listing standards of NASDAQ will require Tokai to have, among other things, a \$4.00 per share minimum bid price upon the closing of the Otic Transaction. Therefore, the reverse stock split may be necessary in order to consummate the Otic Transaction.

Principal Effects of the Reverse Stock Split

Increase in authorized and unissued shares

The reverse stock split will not affect the number of authorized shares of Tokai common stock that will continue to be authorized pursuant to the Amended and Restated Certificate of Incorporation of Tokai. As a result, one of the effects of the reverse stock split will be to effectively increase the proportion of authorized shares which are unissued relative to those which are issued. This could result in Tokai's management being able to issue more shares without further stockholder approval.

Tokai currently has no plans to issue shares, other than in connection with the Otic Transaction and the Equity Financing, and to satisfy obligations under existing outstanding equity awards and Otic share awards to be assumed, from time to time as these options are exercised.

Potential increase in investor interest

On January 20, 2017, Tokai common stock closed at \$0.98 per share. An investment in Tokai common stock may not appeal to brokerage firms that are reluctant to recommend lower priced securities to their

[Table of Contents](#)

clients. Investors may also be dissuaded from purchasing lower priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, the analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower priced stocks. Also, the Tokai board of directors believes that most investment funds are reluctant to invest in lower priced stocks.

Risks of the Reverse Stock Split

There are risks associated with the reverse stock split, including that the reverse stock split may not result in an increase in the per share price of Tokai common stock. Tokai cannot predict whether the reverse stock split will increase the market price for Tokai common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of Tokai common stock after the reverse stock split will rise in proportion to the reduction in the number of shares of Tokai common stock outstanding before the reverse stock split;
- the reverse stock split will result in a per share price that will attract brokers and investors who do not trade in lower priced stocks; or
- the market price per share will meet the requirements of NASDAQ for inclusion for trading on The NASDAQ Global Market, including the \$4.00 minimum bid price upon the closing of the transaction, or, of meeting the continued listing requirements of NASDAQ going forward.

The market price of Tokai common stock will also be based on performance of Tokai and other factors, some of which are unrelated to the number of shares outstanding. If the reverse stock split is effected and the market price of Tokai common stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of Tokai may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of Tokai common stock could be adversely affected by the reduced number of shares that would be outstanding after the reverse stock split.

The form of amendment to the Amended and Restated Certificate of Incorporation of Tokai effecting the reverse stock split is set forth in *Annex C* to this proxy statement.

The reverse stock split will be effected simultaneously for all outstanding shares of Tokai common stock. The reverse stock split will affect all of the Tokai stockholders uniformly and will not affect any stockholder's percentage ownership interests in Tokai, except to the extent that the reverse stock split results in any of the Tokai stockholders owning a fractional share. Common stock issued pursuant to the reverse stock split will remain fully paid and nonassessable. The reverse stock split does not affect the total proportionate ownership of Tokai following the transaction. The reverse stock split will not affect Tokai continuing to be subject to the periodic reporting requirements of the Exchange Act.

Procedure for Effecting Reverse Stock Split and Exchange of Stock Certificates

If Tokai stockholders approve the amendment to the Amended and Restated Certificate of Incorporation of Tokai effecting the reverse stock split, and if the Tokai board of directors still believes that a reverse stock split is in the best interests of Tokai and its stockholders, Tokai will file an amendment to the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware effecting such reverse stock split at such time as the Tokai board of directors has determined to be the appropriate split effective time. The Tokai board of directors may delay effecting the reverse stock split without resoliciting stockholder approval, provided that the reverse stock split is effected within _____ months of the date of the special meeting. Beginning at the split effective time, each certificate representing pre-split shares will be deemed for all corporate purposes to evidence ownership of post-split shares.

[Table of Contents](#)

As soon as practicable after the split effective time, stockholders will be notified that the reverse stock split and/or corporate name change have been effected. Tokai expects that the Tokai transfer agent will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-split shares will be asked to surrender to the exchange agent certificates representing pre-split shares in exchange for certificates representing post-split shares in accordance with the procedures to be set forth in a letter of transmittal to be sent by Tokai. In the event that the Otic Transaction is consummated, the certificates reflecting the post-split shares will also reflect the change of the Tokai corporate name to "OticPharma, Inc." No new certificates will be issued to a stockholder until such stockholder has surrendered such stockholder's outstanding certificate(s) together with the properly completed and executed letter of transmittal to the exchange agent. Any pre-split shares submitted for transfer, whether pursuant to a sale or other disposition, or otherwise, will automatically be exchanged for post-split shares. Stockholders should not destroy any stock certificate(s) and should not submit any certificate(s) unless and until requested to do so.

TOKAI STOCKHOLDERS SHOULD NOT DESTROY ANY STOCK CERTIFICATE(S) AND SHOULD NOT SUBMIT ANY CERTIFICATE(S) UNTIL REQUESTED TO DO SO.

Fractional Shares

No fractional shares will be issued in connection with the reverse stock split. Stockholders of record who otherwise would be entitled to receive fractional shares because they hold a number of pre-split shares not evenly divisible by the number of post-split shares for which each post-split share is to be reclassified, will be entitled, upon surrender to the exchange agent of certificates representing such shares, to a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of the common stock on The NASDAQ Global Market on the date immediately preceding the split effective time. The ownership of a fractional interest will not give the holder thereof any voting, dividend, or other rights except to receive payment therefor as described herein.

Stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where Tokai is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by Tokai or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

Material U.S. Federal Income Tax Consequences of the Reverse Stock Split

The following discussion is a summary of the material U.S. federal income tax consequences of the proposed reverse stock split to holders of Tokai common stock. This discussion is based on the Internal Revenue Code of 1986, as amended, which we refer to as the *Code*, U.S. Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, which we refer to as the *IRS*, in each case in effect as of the date of this proxy statement. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a holder of Tokai common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the proposed reverse stock split.

This discussion is limited to holders who hold their Tokai common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to the particular circumstances of a Tokai stockholder.

[Table of Contents](#)

including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to holders of Tokai common stock that are subject to special rules, including, without limitation:

- Financial institutions;
- Insurance companies;
- Real estate investment trusts;
- Regulated investment companies;
- Grantor trusts;
- Tax-exempt organizations;
- Dealers or traders in securities or currencies;
- Stockholders who hold common stock as part of a position in a straddle or as part of a hedging, conversion or integrated transaction for U.S. federal income tax purposes or U.S. holders that have a functional currency other than the U.S. dollar;
- Stockholders who actually or constructively own 10% or more of Tokai's voting stock; or
- A non-U.S. holder who is a U.S. expatriate, "controlled foreign corporation" or "passive foreign investment company."

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is the beneficial owner of Tokai common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Accordingly, partnerships (and other entities treated as partnerships for U.S. federal income tax purposes) holding Tokai common stock and the partners in such entities should consult their own tax advisors regarding the U.S. federal income tax consequences of the proposed reverse stock split to them.

In addition, the following discussion does not address the U.S. federal estate and gift tax, alternative minimum tax, or state, local and non-U.S. tax law consequences of the proposed reverse stock split. Furthermore, the following discussion does not address any tax consequences of transactions effectuated before, after or at the same time as the proposed reverse stock split, whether or not they are in connection with the proposed reverse stock split.

STOCKHOLDERS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PROPOSED REVERSE STOCK SPLIT ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Tax Consequences Applicable to U.S. Holders

For purposes of this discussion, a "***U.S. Holder***" is a beneficial owner of Tokai common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation (or any other entity or arrangement treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

[Table of Contents](#)

- a trust if (1) its administration is subject to the primary supervision of a court within the United States and all of its substantial decisions are subject to the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (2) it has a valid election in effect under applicable U.S. Treasury regulations to be treated as a United States person.

The proposed reverse stock split should constitute a “recapitalization” for U.S. federal income tax purposes pursuant to Section 368(a)(1)(E) of the Code. As a result, a U.S. Holder of Tokai common stock generally should not recognize gain or loss upon the proposed reverse stock split for U.S. federal income tax purposes, except with respect to cash received in lieu of a fractional share of Tokai common stock, as discussed below. A U.S. Holder’s aggregate adjusted tax basis in the shares of Tokai common stock received pursuant to the proposed reverse stock split should equal the aggregate adjusted tax basis of the shares of the Tokai common stock surrendered (reduced by the amount of such basis that is allocated to any fractional share of Tokai common stock). The U.S. Holder’s holding period in the shares of Tokai common stock received should include the holding period in the shares of Tokai common stock surrendered. U.S. Treasury Regulations provide detailed rules for allocating the tax basis and holding period of shares of common stock surrendered to shares of received in a recapitalization. U.S. Holders of shares of Tokai common stock acquired on different dates and at different prices should consult their tax advisors regarding the allocation of the tax basis and holding period of such shares.

A U.S. Holder of Tokai common stock that receives cash in lieu of a fractional share of Tokai common stock pursuant to the proposed reverse stock split should recognize capital gain or loss in an amount equal to the difference, if any, between the amount of cash received and the portion of the U.S. Holder’s aggregate adjusted tax basis in the shares of Tokai common stock surrendered that is allocated to such fractional share of Tokai common stock. Such capital gain or loss will be short term if the pre-reverse split shares were held for one year or less at the effective time of the reverse stock split and long term if held for more than one year. No gain or loss will be recognized by us as a result of the proposed reverse stock split.

Tax Consequences Applicable to Non-U.S. Holders

For purposes of this discussion, a “***Non-U.S. Holder***” is a beneficial owner of Tokai common stock that is neither a U.S. Holder nor a partnership (or an entity treated as a partnership for U.S. federal income tax purposes).

Generally, a Non-U.S. Holder will not recognize any gain or loss upon the proposed reverse stock split. Any gain or loss realized with respect to cash received in lieu of a fractional share generally will not be subject to U.S. federal income or withholding tax unless:

- (a) such gain or loss is effectively connected with the Non-U.S. Holder’s conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment maintained by the Non-U.S. Holder),
- (b) the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the proposed reverse stock split and certain other conditions are met, or
- (c) Tokai common stock constitutes a U.S. real property interest by reason of Tokai’s status as U.S. real property holding corporation (“***USRPHC***”) for U.S. federal income tax purposes. Although there can be no assurance, Tokai believes that it is not currently and has not been, and it does not anticipate becoming, a USRPHC.

Gain described in clause (a) above generally will be subject to U.S. federal income tax on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons. A Non-U.S. Holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

[Table of Contents](#)

A Non-U.S. Holder described in clause (b) above will be subject to U.S. federal income tax at a rate of 30% (or, if applicable, a lower treaty rate) on the gain realized with respect to cash received in lieu of a fractional share, which may be offset by certain U.S. source capital losses of the Non-U.S. Holder recognized in the year the reverse stock split is effected, even though the Non-U.S. Holder is not considered a resident of the United States.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of cash made in lieu of a fractional share of Tokai common stock may, under certain circumstances, be subject to information reporting and backup withholding. To avoid backup withholding, each holder of Tokai common stock that does not otherwise establish an exemption should furnish its taxpayer identification number and comply with the applicable certification procedures.

Backup withholding is not an additional tax and amounts withheld will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle such holder to a refund, provided the required information is timely furnished to the IRS. Holders of Tokai common stock should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Vote Required; Recommendation of Tokai Board of Directors

The Tokai board of directors has declared this proposed amendment to be advisable and has recommended that this proposed amendment be presented to Tokai's stockholders for approval.

Presuming a quorum is present, of the Reverse Stock Split Proposal requires the affirmative vote of a majority of the shares of Tokai common stock outstanding and entitled to vote at the special meeting (broker non-votes and abstentions will have the same effect as voting against the Reverse Stock Proposal).

THE TOKAI BOARD OF DIRECTORS RECOMMENDS THAT THE TOKAI STOCKHOLDERS VOTE "FOR" THE REVERSE STOCK SPLIT PROPOSAL TO APPROVE THE CHARTER AMENDMENT TO EFFECT THE REVERSE STOCK SPLIT PURSUANT TO WHICH A NUMBER OF OUTSTANDING SHARES BETWEEN AND INCLUDING AND TO BE DETERMINED BY THE TOKAI BOARD OF DIRECTORS WOULD BE COMBINED AND RECLASSIFIED INTO ONE SHARE OF TOKAI COMMON STOCK. EACH OF THE SHARE ISSUANCES PROPOSAL, THE REVERSE STOCK SPLIT PROPOSAL AND THE ADJOURNMENT PROPOSAL IS AN INDEPENDENT PROPOSAL; NONE OF THE FOREGOING IS CONDITIONED UPON ANOTHER PROPOSAL. THE APPROVAL OF THE SHARE ISSUANCES PROPOSAL IS REQUIRED TO CONSUMMATE THE OTIC TRANSACTION. THE OTIC TRANSACTION MAY BE CONSUMMATED REGARDLESS OF WHETHER THE TOKAI STOCKHOLDERS APPROVE OR DO NOT APPROVE THE REVERSE STOCK SPLIT PROPOSAL OR THE ADJOURNMENT PROPOSAL.

ADJOURNMENT PROPOSAL

APPROVAL OF ADJOURNMENT OF SPECIAL MEETING

In this proposal, Tokai is asking its stockholders to approve a proposal to authorize the Tokai board of directors, in its discretion, to adjourn the special meeting, if necessary or appropriate, to solicit additional proxies to approve any of the Share Issuances Proposal or the Reverse Stock Split Proposal. If Tokai's stockholders approve the adjournment of the special meeting, Tokai could adjourn the special meeting and any adjourned session of the special meeting and use the additional time to solicit additional proxies, including the solicitation of proxies from stockholders that have previously returned properly executed proxies voting against any of the Share Issuances Proposal or the Reverse Stock Split Proposal. Among other things, approval of this proposal could mean that, even if we had received proxies representing a sufficient number of votes against any of the Share Issuances Proposal or the Reverse Stock Split Proposal such that such proposal would be defeated, we could adjourn the special meeting without a vote on any of the Share Issuances Proposal or the Reverse Stock Split Proposal and seek to convince the holders of those shares to change their votes to votes in favor of such proposal.

Presuming a quorum is present, approval of the Adjournment Proposal requires the affirmative vote of a majority of the shares of Tokai common stock, present in person or represented by proxy and entitled to vote on the subject matter (excluding broker non-votes and abstentions).

THE TOKAI BOARD OF DIRECTORS RECOMMENDS THAT THE TOKAI STOCKHOLDERS VOTE "FOR" THE ADJOURNMENT PROPOSAL TO ADJOURN THE SPECIAL MEETING TO SOLICIT ADDITIONAL PROXIES IF THERE ARE NOT SUFFICIENT VOTES IN FAVOR OF THE SHARE ISSUANCES PROPOSAL OR THE REVERSE STOCK SPLIT PROPOSAL AT THE TIME OF THE SPECIAL MEETING. EACH OF THE SHARE ISSUANCES PROPOSAL, THE REVERSE STOCK SPLIT PROPOSAL AND THE ADJOURNMENT PROPOSAL IS AN INDEPENDENT PROPOSAL; NONE OF THE FOREGOING IS CONDITIONED UPON ANOTHER PROPOSAL. THE APPROVAL OF THE SHARE ISSUANCES PROPOSAL IS REQUIRED TO CONSUMMATE THE OTIC TRANSACTION. THE OTIC TRANSACTION MAY BE CONSUMMATED REGARDLESS OF WHETHER THE TOKAI STOCKHOLDERS APPROVE OR DO NOT APPROVE THE REVERSE STOCK SPLIT PROPOSAL OR THE ADJOURNMENT PROPOSAL.

TOKAI'S BUSINESS

Tokai is a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases. Tokai has focused substantially all of its research and development efforts on the development of galeterone, an oral small molecule, including clinical trials of galeterone for the treatment of patients with metastatic castration-resistant prostate cancer, or mCRPC. Tokai also has a drug discovery program, known as ARDA (androgen receptor degradation agents), under which it was seeking to identify and develop novel compounds for patients with androgen receptor signaling diseases, including prostate cancer, either alone or in combination with other products.

In July 2016, Tokai announced its plan to discontinue ARMOR3-SV, its pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant, following the recommendation made by the trial's independent data monitoring committee, or DMC, in July 2016. Based on a review of all available safety and efficacy data, the DMC determined that the ARMOR3-SV trial would likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival for galeterone versus enzalutamide in men with AR-V7 positive mCRPC. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial.

In addition, in August 2016, Tokai determined to discontinue enrollment in its Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi® (enzalutamide) and not to proceed with its planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga® (abiraterone acetate). Enrollment in the ARMOR3-SV and ARMOR2 trials has now been closed, with only patients in the ARMOR2 trial continuing treatment at this time.

Following the announcement regarding the discontinuation of the ARMOR3-SV trial, in July 2016 Tokai announced that its board of directors approved a plan to reduce the size of its workforce by approximately 60% to a total of 10 full-time equivalent employees. The workforce reduction, which was completed in September 2016, was designed to reduce Tokai's operating expenses while it conducted a review of development options for galeterone and the ARDA program. As of December 31, 2016, Tokai had nine employees.

In September 2016, Tokai announced that its board of directors had initiated a review of strategic alternatives that could result in changes to its business strategy and future operations. As part of this process, which was conducted in parallel with a review of development options for galeterone and the ARDA program, the Tokai board determined to review alternatives with the goal of maximizing stockholder value, including potentially a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets. Tokai entered into the Share Purchase Agreement with Otic and the Otic shareholders as a result of this process.

OTIC'S BUSINESS

Overview

Otic is a clinical-stage, specialty pharmaceutical company focused on the acquisition and development of products for disorders of the ear, nose, and throat ("*ENT*"). Otic has two novel technologies that are initially being developed for conditions of the ear.

OP-01 is a foam-based technology. It is being developed by Otic with the intent to be used as a delivery vehicle for drugs which are to be placed into the ears, as well as the nasal and sinus cavities. OP-01 is currently being developed as an improved treatment option for acute otitis externa ("*AOE*" or "swimmers ear"), a common medical condition of the outer ear canal that globally affects tens of millions of adults and children every year. Otic has completed four clinical trials of OP-01 in 353 subjects, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP-01 that performed similarly to standard of care. Otic is now planning to modify the formulation of OP-01 to create a clinically differentiated, best-in-class product for AOE that is an improvement to the standard of care.

OP-02 is a surfactant-based technology. It was originally developed by Otodyne, Inc. and subsequently licensed to Otic in November 2015. OP-02 is currently being developed as a potential first-in-class treatment option for patients with otitis media ("*OM*") and Eustachian tube dysfunction ("*ETD*"). OM and ETD are common medical conditions of the middle ear that globally affects more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice and is the most frequent reason children are prescribed antibiotics and undergo surgery. OP-02 is a daily nasal spray, designed to improve and maintain the Eustachian tube's ability to drain and ventilate the middle ear. Otic is planning to initiate multiple phase 1 clinical studies of OP-02 in 2017 to explore the safety and tolerability of OP-02, as well as explore how OP-02 affects Eustachian tube function (pharmacodynamics). These phase 1 studies will evaluate single and repeated intranasal doses of OP-02 in adults. Upon completion of these studies, Otic expects that its initial phase 2 studies of OP-02 will focus on prevention of acute, recurrent, and chronic OM in children.

Otic was founded in Israel in 2008. In 2015, Otic established U.S. operations and moved its corporate headquarters to Irvine, California. The executive offices are located at 19900 MacArthur Blvd., Suite 550, Irvine, CA 92612. The telephone number and website for Otic is (949) 238-8090 and www.oticpharma.com.

Otic's Strengths

- *History of Successful Drug Development & Product Registration.* Otic's management team has extensive experience in developing novel, first-in-class products. Otic's Chief Development Officer and Head of Clinical Development & Operations were previously with Allergan and were responsible for successful development and registration of BOTOX® for multiple therapeutic indications around the world, including adult and pediatric spasticity, and chronic migraine. Other members of the Otic management were closely involved with successful development of novel products such as EVISTA® (first-in-class for osteoporosis) and NUEDEXTA® (first-in-class for pseudobulbar affect).
- *Ability to Create Shareholder Value.* Otic's Chairman, Chief Executive Officer, Chief Financial Officer, and VP of Corporate Operations were key members of management from Avanir Pharmaceuticals who together successfully restructured the company and built Avanir into a multi-billion dollar CNS specialty pharmaceutical company with a portfolio of assets.
- *Potential for Multiple Indications.* Both OP-01 and OP-02 can be broadly developed for additional indications, using the current active ingredients or through the addition of new active ingredients.

[Table of Contents](#)

Strategy

Otic's goal is to build a specialty pharmaceutical company that leverages Otic's expertise in development and commercialization to transform treatment paradigms and offer patients suffering from ENT disorders innovative therapies in indications that are underserved by current treatment options. Key elements of Otic's strategy include:

- *Establishing Strong Leadership:* Building a leading specialty pharmaceutical company to transform current treatment paradigms for patients with ENT disorders. Otic has brought together a group of experienced drug developers that Otic believes, when coupled with its proprietary technologies, will allow Otic to potentially develop and commercialize therapeutics that may improve the outcomes for patients suffering from many types of ENT disorders.
- *Leveraging Product Development Expertise.* Creating development programs with the potential to maximize the return on investment by targeting indications that have high unmet clinical needs, including indications that provide Otic the opportunity to pioneer new indications as well as the potential to establish a strong brand equity for Otic's treatments in pediatric and ENT clinics. Goals of the development programs are to gain regulatory approval for proposed indications in the United States and key European markets. In developing its products, Otic plans to collect robust data to support global reimbursement and market access, including burden of illness evidence, clinical trial data, patient reported outcomes, head to head data (direct or indirect, as appropriate), and economic value evidence.
- OP-01 Program Goals
 1. Develop a safe, well-tolerated and clinically differentiated product for AOE that is easy to administer, addresses both ear pain and infection, and disrupts the market by delivering a full course of therapy with a limited number of doses.
 2. Explore additional uses of the foam platform to meet unmet clinical needs for treatment of nasal and sinus conditions using the same or other active ingredients.
- OP-02 Program Goals
 1. Develop a first-in-class treatment for OM that prevents progression to recurrent or chronic OM.
 2. Provide a safe, well-tolerated and effective therapy that improves health outcome and quality of life by restoring ear health, reducing the overuse and misuse of antibiotics, and reducing or preventing invasive surgical treatments such as insertion of tympanostomy tubes in children.
 3. Explore additional uses of the surfactant technology to meet unmet clinical needs for other OM and ETD disorders in both children and adults.
- Corporate Development Goals
 1. Look for opportunities to expand the Otic portfolio with complementary assets and technologies capable of increasing shareholder value.
 2. Explore opportunities to partner with other companies that can help develop and commercialize Otic's products around the world.

Pipeline Chart



OP-01 for Acute Otitis Externa (AOE)

AOE (or “swimmer’s ear”) is a generalized inflammation of the epithelium of the external ear canal that may also involve the pinna and/or the tympanic membrane (eardrum). The vast majority of AOE cases are due to bacterial infections, with *Pseudomonas aeruginosa* and *Staphylococcus aureus* being the most common pathogens. The condition is commonly associated with pain and characterized by redness of the ear canal (erythema), swelling of the tissue (edema), increased secretion of fluid, and shedding or peeling of the skin (desquamation of the epithelium). AOE occurs in all age groups and is more frequently observed in the summer months as well as in hot and humid environments. The most common treatment for AOE is antibiotics, with or without steroids, analgesics and avoiding ears being immersed underwater (e.g., swimming). Ear treatments are generally supplied in the form of liquids with several drops administered into each infected ear multiple times per day for a week or longer. In the U.S. alone, more than 5 million prescriptions for ear anti-infective products are prescribed every year, mostly for the treatment of AOE.

The current market leader in the ear anti-infective market is CIPRODEX[®], marketed by Alcon, which according to IMS Health generated over \$400 million in sales in the United States in 2015. It is a liquid suspension containing the antibiotic ciprofloxacin and the steroid dexamethasone. It is administered as four drops per infected ear, twice-daily over seven days for a total of 14 doses (56 drops placed into the ear canal over the course of a week). There are numerous other branded and generic ear anti-infectives, but none of these are clinically differentiated from CIPRODEX. Although effective when administered properly, liquid drops like these anti-infectives can be a challenge to administer into the ear, particularly in children. Proper administration requires the patient to lie down with the infected ear pointed upward, careful placement of multiple drops into the infected ear, manipulation of the ear lobe to move the liquid down into the ear canal, and the patient should remain still with the infected ear pointed upwards after applying the product for a period of time to prevent the medication from draining out of the ear. In addition, rapid resolution of otalgia (ear pain) is not achieved with any of the currently approved anti-infective products, even those that also contain an anti-inflammatory (e.g., steroid) in the formulation, like CIPRODEX.

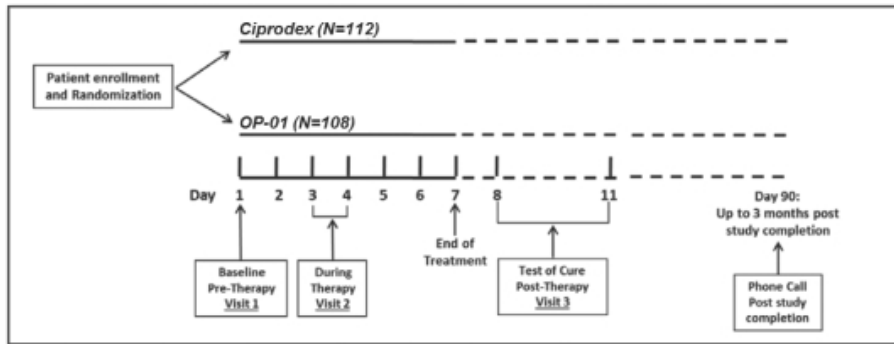
Foam formulations such as OP-01 are becoming a prominent delivery system for topical drugs due to the intrinsic advantages of the platform: easy and fast administration, visibility of product during and after the administration, and complete coverage of large and variable surface areas as the product expands and molds to the shape of the cavity. In addition, foam formulations can remain in place for longer periods of time, increasing

[Table of Contents](#)

residence time of drugs at target sites. Finally, foam-based ear products can be administered while the patient is standing or sitting and do not require holding the head in any special orientation for a period of time.

Otic conducted four clinical trials of its first generation (antibiotic only) formulation of OP-01 that it believes supported the utility of OP-01. Data from the most recent clinical trial was announced in January 2015. The study was a 220 patient, phase 2, randomized, multicenter, parallel, active comparator trial in 220 AOE patients ages six months and older. During this trial, OP-01 which contains 0.3% ciprofloxacin was administered once-daily for 7 days (7 doses) while the active comparator (CIPRODEX), which contains 0.3% ciprofloxacin and 0.1% dexamethasone was administered twice-daily for 7 days (14 doses). The primary endpoint of the study was clinical cure, defined as score = 0 for erythema, edema, tenderness, ear discharge (otorrhea), and no further antibiotic required. safety and efficacy of OP-01 was found to be similar (non-inferior) to CIPRODEX, even though OP-01 contained no steroid and utilized 50% fewer doses over the week-long course of therapy.

Phase 2 Design and Summary



Phase 2 Study OP-004-00 Key Results

Key Result	Treatment Arm	
	OP-01	CIPRODEX®
Study Completers	88%	92%
Subjects reports 1 or more Adverse Event	20.9%	15.5%
Subjects reports 1 or more Serious Adverse Event ¹	1	0
Clinical Cure (3-measure), mITT ²	84.8%	87%
Clinical Cure (5-measure), mITT ³	81.6%	88.2%
Pathogen eradication, micITT	96.4%	96.9%
Time to end of pain, mITT	3.6 days	4.4 days

1. Determined to be not related to the study drug, patient died 3-months after completing the study due to cardiac arrest
2. Defined as score = 0 for erythema, edema and tenderness
3. Defined as score = 0 for erythema, edema, tenderness, ear discharge (otorrhea), and no further antibiotic needed

mITT= subjects who met all inclusion/exclusion criteria, including a positive baseline bacterial culture for one of the pathogens related to AOE, used at least one dose of study product and returned for at least one post-baseline evaluation visit

micITT= subjects from the mITT group who had a positive baseline bacterial culture for one of the pathogens related to AOE

[Table of Contents](#)

In 2016, Otic stopped further development of the first-generation, antibiotic-only product and began development of a second-generation formulation of OP-01 which will include both an antibiotic plus a second active ingredient to address ear pain. The goal for this second-generation OP-01 formulation is to produce a clinically differentiated product that rapidly resolves ear pain (an unmet need in AOE), as well as eradicates the infection with fewer than 7 days of dosing. Otic believes a product of this nature would meaningfully improve upon the standard of care and may become a best-in-class treatment option for AOE.

OP-02 for Otitis Media

Inflammation of the middle ear is referred to as Otitis Media (OM), which is a generic term without reference to a specific etiology or pathogenesis and best regarded as a spectrum of diseases. In developed countries, OM is a very common condition and a leading cause of healthcare visits and the prescribing of antibiotics. Common forms of OM are acute OM (AOM) and otitis media with effusion (OME). Both AOM and OME can re-occur episodically or persist for long periods of time. If reoccurrence is frequent (i.e., three episodes within six months), the patient is diagnosed with recurrent OM. If fluid persists in the middle ear for longer than three months, then the patient is diagnosed with chronic OM.

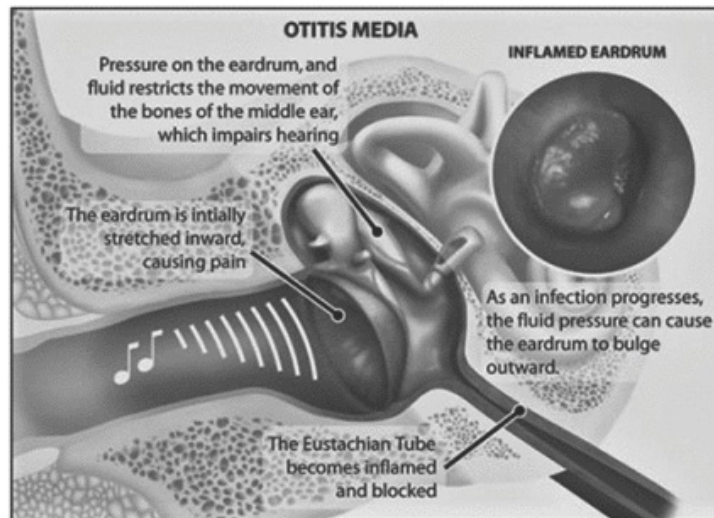
AOM is usually a short-term inflammation of the middle ear, characterized by the sudden onset of one or more signs or symptoms of acute middle ear inflammation (e.g., ear pain, tugging at the ear, fever or irritability) in the presence of middle ear effusion. AOM is often preceded by upper respiratory symptoms including cough and rhinorrhea. Micro-organisms (viral or bacterial) in the nasopharynx may reflux into the middle ear, where they adhere and colonize resulting in an ear infection. AOM is extremely common in young children, many of whom will have multiple AOM episodes (recurrent AOM) over the course of months or even years.

OME is also very common and can affect both children and adults. OME is characterized by a non-purulent (non-infected) effusion of the middle ear without sudden onset of signs or symptoms of an acute ear infection. Symptoms usually involve conductive hearing loss or aural fullness caused by impaired transduction of sounds waves through the fluid-filled middle ear, but typically without pain or fever. OME often follows an AOM episode and can last for several months or up to a year, which can result in speech and learning delays in children and other morbidities in both children and adults. There are several predisposing factors that have been associated with OME including environmental (e.g., bottle feeding, day-care setting, allergies to common environmental entities, cigarette smoke), age (higher incidence in pre-school age children), and Eustachian tube dysfunction (ETD). Like AOM, patients can experience multiple OME episodes over the course of months or years.

An important component of middle ear health is a normally functioning Eustachian tube. The Eustachian tube is a small cilia-lined passageway that connects the middle ear to back of the nasal cavity (nasopharynx). Its primary functions are to protect, drain, and ventilate the middle ear. Normally, it is collapsed, preventing material from entering the middle ear. The Eustachian tube opens periodically upon swallowing, chewing, yawning, or when a pressure differential exists between the middle ear and the external environment. When the Eustachian tube becomes blocked or does not open normally, Eustachian tube dysfunction (ETD) occurs.

[Table of Contents](#)

Pathophysiology of Otitis Media:



The pathophysiology of OM and ETD are closely related. Both conditions can arise as a result of upper respiratory tract infections, allergies, and other inflammatory mediators and one condition can perpetuate the other condition. There are more than 700 million cases of OM and ETD around the world every year, half of which occur in children under 5 years of age. In the U.S. alone, there were more than 18 million visits to physicians during 2010 related to OM and ETD. It is one of the most common diseases seen in Pediatric and ENT practices and is the most frequent reason children consume antibiotics or undergo surgery.

To date, no drug product has been approved for OM. Antibiotics are commonly used to treat AOM patients who present with signs and symptoms of infection, but antibiotics have no effect on viral infections or OME which is a non-infectious condition. More importantly, antibiotics do not prevent recurrent AOM, recurrent OME or chronic OME. Topical steroids, antihistamines, and decongestants have not been shown to be effective, particularly in OME and as such, the American Academy of Otolaryngology—Head and Neck Surgery recommend against use of these drugs in patients. The only option today to treat and possibly prevent recurrent or chronic OM, is to perform a surgery where the tympanic membrane is perforated to improve drainage and ventilation of the middle ear (myringotomy or tympanostomy tube insertions). However, surgery is not always an effective solution for all patients as many continue to suffer with OM or its complications and sometimes can require repeat surgeries. Managing recurrent and chronic OM drives billions of dollars in healthcare costs and results in millions of surgical procedures in children and adults around the world. There is a clear unmet need for a non-antibiotic, non-surgical option for patients.

In 2016, the FDA permitted marketing of a medical device that uses a small intranasal balloon inserted into the Eustachian tube to treat persistent ETD in adults. However, like OM, no drug product has been approved for the prevention of ETD.

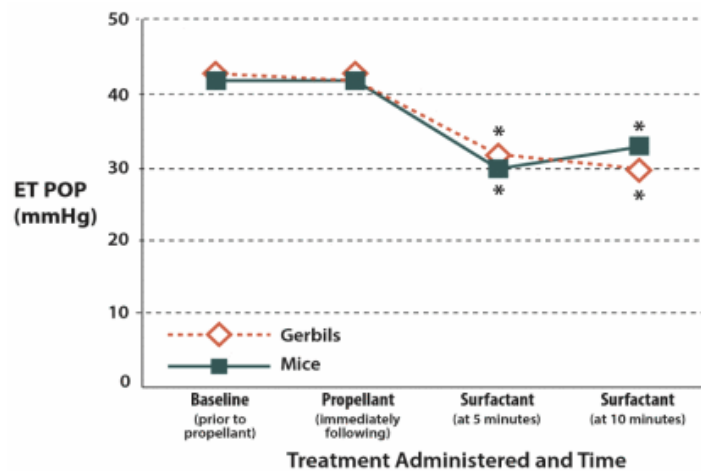
OP-02 is a novel combination drug product, comprised of two active ingredients, the surfactant dipalmitoylphosphatidylcholine (DPPC) and a spreading agent cholesteryl palmitate (CP), and formulated with a propellant for easy administration. The product is sprayed through the nostrils towards the opening of the Eustachian tube at the lower back of the nasal cavity. The surfactant and spreading agent act to lower the surface tension at the opening and along the Eustachian tube, causing a “de-sticking” of the tissue and restoration of normal Eustachian tube function.

[Table of Contents](#)

Surfactants are ubiquitous and well-understood endogenous compounds present in human nasal passages, the Eustachian tube, and lung tissues, as well as in human milk and amniotic fluid. Surfactants have been evaluated under the hypothesis that exogenous administration of surfactant to a mucosal lined lumen such as the alveoli would result in de-sticking of the tissue and allowance of oxygen exchange in the lungs. In the case of the Eustachian tube, it is known that the quantity of surfactants along the Eustachian tube of children with OM is significantly reduced when compared to otologically healthy children. Also, the Eustachian tube surface tension in patients with OM is higher than reported for patients with healthy Eustachian tubes, causing the luminal surfaces to stick together. Indeed, reduction in Eustachian tube luminal surface tension and passive opening pressure (“POP”), as well as improved Eustachian tube function was demonstrated in a study of six cynomolgous monkeys who received injections of the calf lung surfactant extract INFASURF® directly into the Eustachian tube lumen.

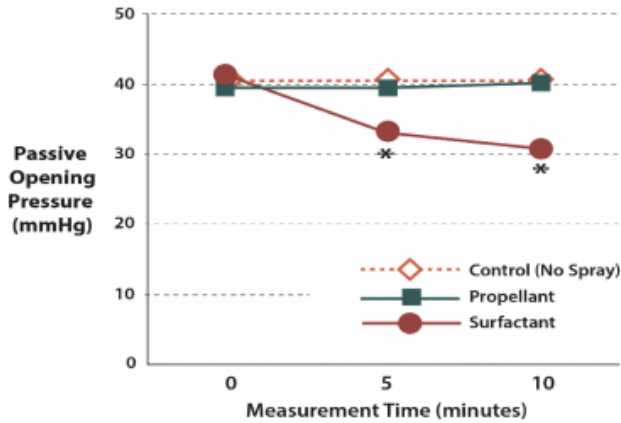
The positive effects of OP-02 on Eustachian tube function have been observed in preclinical animal studies. Meaningful reductions in POP of healthy Eustachian tube, as well as meaningful reduction in severity and duration of OM episodes in three animal species after treatment with OP-02 have been observed. In two separate animal-model experiments, the investigators studied the effects of intranasal administration of an early formulation of OP-02 on Eustachian tube POP of the left ear as compared to propellant in healthy Mongolian gerbils and albino mice. In both animal species, administration of OP-02 resulted in significant ($p < 0.001$) reductions in mean Eustachian tube POP measurements at both the 5 and 10-minute assessment times compared to baseline and immediately following propellant alone administration (Figures 1, 2 and 3). Among the gerbils, the mean (standard error [SE]) Eustachian tube POP values (in millimeters of mercury [mmHg]) were 42.8 (2.29) at baseline, 42.43 (2.36) after propellant, 31.76 (1.74) at 5 minutes after surfactant, and 29.3 (1.51) at 10 minutes after surfactant. Similar findings were noted in the mice: mean (SE) Eustachian tube POP values were 42.02 (1.22) at baseline, 42.02 (1.22) after propellant, 29.77 (1.69) at 5 minutes after surfactant, and 32.79 (1.77) at 10 minutes after surfactant.

Figure 1: Mean Passive Opening Pressures in Gerbil and Mice at Baseline, Immediately after Propellant, and at 5 and 10 Minutes after Surfactant Administration (Experiment 1)



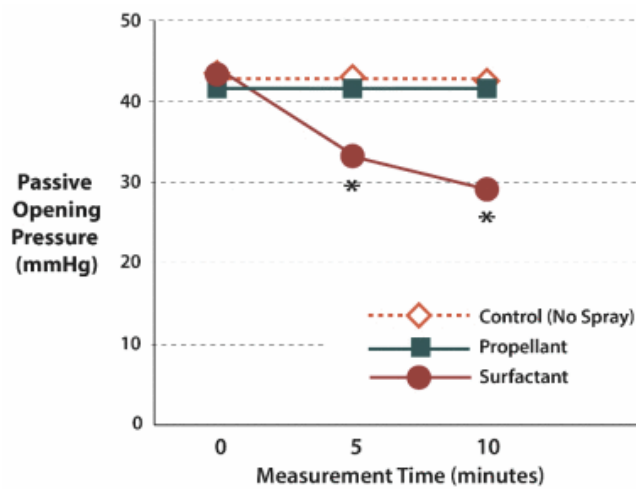
* $p < 0.05$ for surfactant treatment (each timepoint and animal group) compared to baseline and following propellant administration.

Figure 2: Mean Passive Opening Pressure in Gerbils (Experiment 2)



* $p < 0.05$ for surfactant treatment (at 5 and 10 minute timepoints) compared to gerbils treated with control (no spray) or propellant alone.

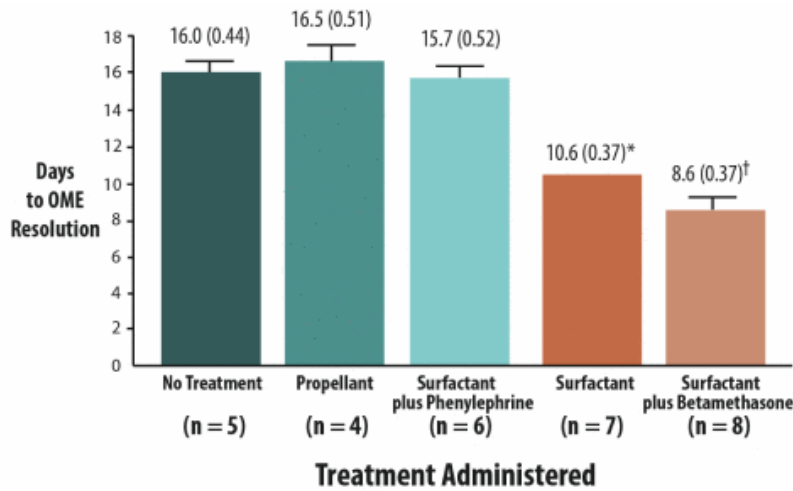
Figure 3: Mean Passive Opening Pressures in Mice (Experiment 2)



* $p < 0.05$ for surfactant treatment (at 5 and 10 minute timepoints) compared to mice treated with control (no spray) or propellant alone.

In a study of gerbils with experimentally induced OME, treatment with OP-02 alone or in combination with the steroid betamethasone resulted in significantly ($p < 0.05$) shorter durations of OME when compared to no treatment (control), propellant alone (placebo), or surfactant plus phenylephrine when assessed by otomicroscopy (Figure 4) or by tympanometry (Figure 5).

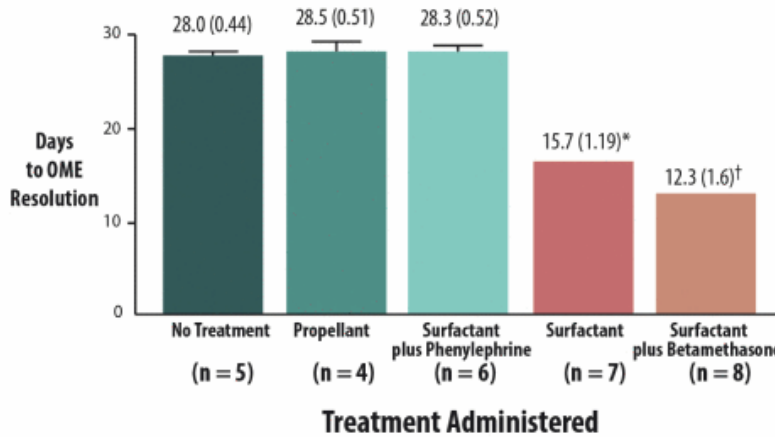
Figure 4: Days to OME Resolution, by Otomicroscopy, once daily administration



* p<0.05 compared with no treatment, propellant alone, or surfactant plus phenylephrine.

+ p<0.05 compared with no treatment, propellant alone, or surfactant plus phenylephrine.

Figure 5: Days to OME Resolution, by Tympanometry, once daily administration



* p<0.05 compared with no treatment, propellant alone, or surfactant plus phenylephrine.

+ p<0.05 compared with no treatment, propellant alone, or surfactant plus phenylephrine.

In a study of experimentally induced AOM in chinchillas, the use of OP-02 was associated with a marked reduction in the severity and duration of AOM. Furthermore, quantitative cultures of middle ear fluid showed dramatic decreases in bacterial colonization with intranasal surfactant treatment alone (i.e., no antibiotics were administered in this study). Based on these findings, Otic believes that resolution of effusion may occur significantly earlier with surfactant treatment than with placebo. The data suggest that enhancement/restoration of Eustachian tube function is beneficial in acute bacterial OM.

[Table of Contents](#)

Prior to licensing rights to OP-02, nine humans with various OM and ETD conditions were treated with OP-02 by the inventors. This human experience was captured as case studies and reported to the FDA. Based on these case studies, in conjunction with the preclinical animal data, Otic believes that a product of this type may have utility in the prevention of OM and management of ETD in children and adults.

Otic plans to initiate a phase 1 clinical study to explore safety, tolerability, and pharmacodynamic effects of OP-02 in subjects in the first half of 2017. The study is expected to enroll 16 subjects (32 ears) into a randomized, double-blind, placebo-controlled, cross-over design, using a single intranasal dose. The primary assessments for this study are expected to include evaluations of safety and tolerability. In addition, using a technique of continuous tympanic impedance, subject's Eustachian tube function (pharmacodynamic assessment of the opening and closing of the Eustachian tube) will be evaluated over a 6-minute period during compression and decompression while in a hypobaric/hyperbaric pressure chamber.

Intellectual Property

Otic's success depends in part on its ability to obtain and maintain proprietary protection for its product candidates, novel discoveries, product technologies and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing Otic's proprietary rights. Otic seeks to protect its product candidates by, among other methods, filing U.S. and foreign patent applications related to its proprietary technology, inventions and improvements that are important to the development and implementation of its business. Otic also relies on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain Otic's proprietary protection for Otic's product candidates.

Otic's intellectual property portfolio includes patents and patent applications with claims directed towards Otic's OP-01 and OP-02 product candidates and claiming pharmaceutical preparations with methods of use. For OP-01, Otic owns or has exclusive rights to three U.S. and seven foreign patents (Canada, France, Germany, Israel, Italy, Spain, UK). The last to expire issued patent in the U.S. will expire in September 2027, including patent term adjustment. In addition, Otic owns or has exclusive rights to two U.S. patent applications, one of which has recently been allowed, and three foreign patent applications (Canada, China, and Europe). The recently allowed U.S. patent application will expire in December 2033, absent any adjustments or extensions. For OP-02, Otic has exclusive rights to seven U.S. and two foreign patents (Canada, Mexico). The last to expire patent in the U.S. will expire in November 2019. In addition, Otic owns or has exclusive rights to one U.S. patent application, one International (PCT) patent application, and three foreign patent applications, one of which has been allowed (Europe). The pending U.S. patent application will expire in November 2036, absent any adjustments or extensions.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

Otic also protects its proprietary information by requiring its employees, consultants, contractors and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. In addition, Otic also requires confidentiality or service agreements from third parties that receive confidential information or materials.

License Agreement with Otodyne, Inc.

In November 2015, Otic entered into a license agreement with Scientific Research and Development, Inc. and Otodyne, Inc. granting Otic exclusive worldwide rights to develop and commercialize OP-02. Under the terms of the agreement, Otic is obligated to use commercially reasonable efforts to seek approval for and

[Table of Contents](#)

commercialize at least one product for otitis media in the U.S. and key European markets (France, Germany, Italy, Spain, and the United Kingdom). Otic is responsible for prosecuting, maintaining, and enforcing all intellectual property and will be the sole owner of improvements.

In January 2016, Otodyne completed transfer of all technology, including the active IND, to Otic. Otic is obligated to pay up to \$42.1 million in development and regulatory milestones if OP-02 is approved for three indications in the U.S., two in Europe, and two in Japan. Otic is also obligated to pay up to \$36 million in sales based milestones, beginning with sales exceeding \$1.0 billion in a calendar year. Otic is also obligated to pay a tiered royalty for a period up to eight years, on a country-by-country basis. The royalty ranges from low-single to mid-single percent of net sales.

TOKAI'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of Tokai's financial condition and results of operations together with the section entitled "Selected Historical and Unaudited Pro Forma Combined Financial Information," beginning on page 17 of this proxy statement, and Tokai's consolidated financial statements and related notes included elsewhere in this proxy statement. This discussion and other parts of this proxy statement contain forward-looking statements that involve risks and uncertainties, such as statements of Tokai's plans, objectives, expectations and intentions. Tokai's actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections entitled "Cautionary Statement Regarding Forward-Looking Information" and "Risk Factors," beginning on pages 64 and 29, respectively, of this proxy statement.

Overview

Tokai is a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases. Tokai has focused substantially all of its research and development efforts on the development of galeterone, an oral small molecule, including clinical trials of galeterone for the treatment of patients with metastatic castration-resistant prostate cancer, or mCRPC. Tokai also has a drug discovery program, known as ARDA (androgen receptor degradation agents), under which it was seeking to identify and develop novel compounds for patients with androgen receptor signaling diseases, including prostate cancer, either alone or in combination with other products.

In July 2016, Tokai announced its plan to discontinue ARMOR3-SV, its pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant, following the recommendation made by the trial's independent data monitoring committee, or the DMC, in July 2016. Based on a review of all available safety and efficacy data, the DMC determined that the ARMOR3-SV trial would likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival for galeterone versus enzalutamide in men with AR-V7 positive mCRPC. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial. All patients enrolled in the ARMOR3-SV clinical trial discontinued treatment during October 2016.

Following the announcement regarding the discontinuation of the ARMOR3-SV trial, in July 2016 Tokai announced that the Tokai board had approved a plan to reduce the size of its workforce by approximately 60% to a total of 10 full-time equivalent employees. The workforce reduction, which was completed in September 2016, was designed to reduce Tokai's operating expenses while it conducted a review of development options for galeterone and the ARDA program. Tokai incurred \$1.2 million of expenses during the three months ended September 30, 2016 related to the workforce reduction including severance, benefits and related costs of which \$0.5 million and \$0.7 million were recorded in research and development expenses and general and administrative expenses, respectively. Tokai paid \$0.3 million of these costs during the three months ended September 30, 2016 and expects that it paid \$0.6 million in the fourth quarter of 2016, and will pay \$0.3 million in the first quarter of 2017.

In addition, in August 2016, Tokai determined to discontinue enrollment in its Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi® (enzalutamide) and not to proceed with its planned trials of galeterone. While no new patients are being enrolled in the ARMOR 2 trial, we continue to follow the patients who remain in the ARMOR2 trial.

In September 2016, Tokai announced that its board of directors had initiated a review of strategic alternatives that could result in changes to its business strategy and future operations. As part of this process, which was conducted in parallel with the review of development options for galeterone and the ARDA program,

[Table of Contents](#)

the Tokai board determined to review alternatives with the goal of maximizing stockholder value, including potentially a sale of the company, a reverse merger, a business combination or a sale, license or other disposition of company assets. Tokai entered into the Share Purchase Agreement with Otic and the Otic shareholders as a result of this process.

Financial Operations Overview

Revenue

To date, Tokai has not generated any revenue from product sales and does not expect to generate any revenue from the sale of products in the near future. If Tokai's development efforts for galeterone or other product candidates that it may develop in the future are successful and result in regulatory approval or license or collaboration agreements with third parties, Tokai may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that it may enter into with third parties.

Operating Expenses

The majority of Tokai's operating expenses consist of research and development activities and general and administrative costs.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with Tokai's product research and development efforts, include the following:

- third-party contract costs relating to research, formulation and manufacturing, preclinical studies and clinical trial activities;
- third-party contract costs relating to development of a companion diagnostic test for use with galeterone, including the AR-V7 clinical trial assay that was used to identify eligible patients for ARMOR3-SV;
- personnel costs, including salaries, related benefits and stock-based compensation for personnel engaged in research and development functions;
- consulting fees paid to third parties;
- costs related to compliance with regulatory requirements;
- payments made under Tokai's third-party licensing agreements; and
- allocated facility-related costs.

Tokai typically uses its employee and infrastructure resources across its development programs. Tokai tracks outsourced development costs by product candidate or development program, but Tokai does not allocate personnel costs, payments made under its licensing agreements or other internal costs to specific development programs or product candidates. These costs are included in unallocated research and development expenses in the tables below.

Research and development activities are central to Tokai's business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. To date, Tokai has focused substantially all of its research and development efforts on the development of galeterone. Tokai incurred total research and development expenses of \$32.6 million for the year ended December 31, 2015, \$14.6 million for the year ended December 31, 2014 and \$12.2 million for the year ended December 31, 2013. Tokai incurred total research and development expenses of \$24.0 million for the nine months ended September 30, 2016 and \$24.9 million for the nine months ended September 30, 2015. Tokai anticipates that

[Table of Contents](#)

overall research and development expenses will decrease in the near future compared to prior periods due to the discontinuation of its ARMOR3-SV clinical trial and discontinuation of enrollment in the ARMOR2 expansion trial pending Tokai's review of potential paths forward for galeterone and its ARDA program. However, if Tokai determines to further develop galeterone, proceed with its ARDA program, or both, following its review of development options, Tokai anticipate that it would continue to incur significant research and development expenses as it conduct clinical trials and NDA-enabling activities for galeterone or future product candidates.

In July 2016 Tokai announced its decision to discontinue ARMOR3-SV, its pivotal Phase 3 clinical trial of galeterone, following the recommendation of the trial's independent data monitoring committee and ceased enrollment in this trial. Tokai is analyzing the unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and its ARDA program. Tokai cannot determine with certainty the duration and completion costs of ARMOR3-SV or any future clinical trials of its product candidates or if, when, or to what extent Tokai will generate revenue from the commercialization and sale of any of its product candidates that obtain regulatory approval. Tokai may never succeed in achieving regulatory approval for any of its product candidates. The duration, costs and timing of clinical studies and development of its product candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of its ongoing clinical trials as well as any additional clinical trials and other research and development activities that Tokai may conduct;
- future clinical trial results;
- uncertainties in clinical trial design and patient enrollment rate;
- significant and changing government regulation and regulatory guidance;
- the timing and receipt of any regulatory approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of galeterone or any future product candidates could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the U.S. Food and Drug Administration, or the FDA, or another regulatory authority were to require Tokai to conduct clinical trials beyond those that Tokai anticipates will be required for the completion of clinical development of a product candidate, if Tokai experiences significant delays in patient enrollment in any of its clinical trials, if Tokai is required to enroll more patients than it currently anticipates in order to complete any of its clinical trials, or if Tokai is required to make any changes to the formulation of, or the manufacturing process for, a product candidate, Tokai could be required to expend significant additional financial resources and time on the completion of development and receipt of regulatory approval.

General and Administrative Expenses

General and administrative expenses consist of personnel costs, including salaries, related benefits and stock-based compensation expense, of its executive, finance, business and corporate development and other administrative functions. General and administrative expenses also include professional fees for auditing, tax and legal services, including legal expenses to pursue protection of its intellectual property, pre-commercialization costs, insurance costs, travel expenses and allocated facility-related costs.

Interest and Other Income (Expense), net

Interest and other income (expense), net, consists of interest income and miscellaneous income and expense unrelated to its core operations. Interest income consists of interest earned on its cash and investments. Tokai's interest income has not been significant due to low interest earned on invested balances.

[Table of Contents](#)

Income Taxes

Since Tokai's inception in 2004, Tokai has not recorded any U.S. federal or state income tax benefits for either the net losses incurred or its earned research and development tax credits, due to the uncertainty of realizing a benefit from those items in the future. As of December 31, 2015, Tokai had federal and state net operating loss carryforwards of \$27.9 million and \$24.2 million respectively. Tokai's federal and state net operating loss carryforwards begin to expire in 2024 and 2030, respectively. Tokai also had federal and state research and development tax credit carryforwards of \$1.0 million and \$0.4 million, respectively, as of December 31, 2015, which begin to expire in 2025 and 2023, respectively. Tokai's federal and state net operating loss carryforwards do not yet include the effect of research and development expenses of \$96.1 million that it has capitalized for income tax purposes as of December 31, 2015.

Critical Accounting Policies and Significant Judgments and Estimates

Tokai's management's discussion and analysis of its financial condition and results of operations is based on its consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of Tokai's consolidated financial statements and related disclosures requires it to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Tokai believes that the estimates, assumptions and judgments involved in the accounting policies described below may have the greatest potential impact on Tokai's financial statements and, therefore, consider these to be Tokai's critical accounting policies. Accordingly, Tokai evaluates its estimates and assumptions on an ongoing basis. Tokai's actual results may differ from these estimates under different assumptions and conditions. See also Note 2, "Summary of Significant Accounting Policies" appearing in Tokai's audited consolidated financial statements and Tokai's unaudited interim consolidated financial statements, included elsewhere in this proxy statement for information about these critical accounting policies, as well as a description of Tokai's other significant accounting policies.

Research and Development Expenses

Research and development costs are expensed as incurred. Included in research and development expenses are salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Tokai's research and development activities, including manufacturing expenses and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials. Tokai expenses raw materials used to manufacture its drug substance when received.

As part of the process of preparing Tokai's consolidated financial statements, Tokai is required to estimate its accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with its personnel and outside vendors to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the services when Tokai has not yet been invoiced or otherwise notified of the actual costs. The majority of Tokai's service providers invoice Tokai in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. Tokai makes estimates of its accrued expenses as of each balance sheet date in its consolidated financial statements based on facts and circumstances known to it at that time. Examples of estimated accrued research and development expenses include fees paid to:

- clinical research organizations in connection with clinical trials;
- investigative sites or other providers in connection with clinical trials;
- Qiagen Manchester Limited, or Qiagen, in connection with the development of the AR-V7 clinical trial assay and companion diagnostic test;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

[Table of Contents](#)

Tokai bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple clinical research organizations and investigative sites that manage and conduct clinical trials on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to Tokai's vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, Tokai estimates that the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from Tokai's estimate, Tokai adjusts the accrual or amount of prepaid expense accordingly. Although Tokai does not expect its estimates to be materially different from amounts actually incurred, Tokai's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in Tokai reporting amounts that are too high or too low in any particular period. For the years ended December 31, 2015, 2014 and 2013, Tokai has not made any material adjustments to its prior estimates of accrued research and development expenses.

Accounting for Stock-Based Compensation

Tokai measures all stock options and other stock-based awards granted to employees and directors at the fair value on the date of the grant. The fair value of the awards is recognized as compensation expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions, while the graded vesting method is applied to all grants with both service and performance conditions. For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of the unvested portion of the awards is re-measured using the then-current fair value of the award.

Tokai classifies its stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to September 2014, Tokai was a privately-held company and lacked company-specific historical and implied volatility information. Therefore, Tokai estimated its expected volatility based on the historical volatility of its publicly traded peer companies. Tokai expects to continue to do so until such time as Tokai has adequate historical data regarding the volatility of its traded stock price following its initial public offering. The expected term assumption is based on the "simplified method" for estimating the expected term for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to U.S. Treasury bond yields at or near the time of grant for time periods similar to the expected term of the award. The relevant data used to determine the value of the stock option grants on a weighted average basis is as follows:

	Year Ended December 31,		
	2015	2014	2013
Risk-free interest rate	1.79%	1.83%	1.72%
Expected term (in years)	6.01	5.95	5.98
Expected volatility	74.2%	79.4%	79.7%
Expected dividend yield	0%	0%	0%

The assumptions used in determining the fair value of stock-based awards represent Tokai's best estimates, but the estimates involve inherent uncertainties and the application of Tokai's judgment. As a result, if factors change and Tokai uses significantly different assumptions or estimates, Tokai's stock-based compensation expense

[Table of Contents](#)

could be materially different in the future. Tokai recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, Tokai considered its historical experience of actual forfeitures to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from its estimate, Tokai may be required to record adjustments to stock-based compensation expense in future periods.

JOBS Act

Tokai is an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years from the date of its initial public offering. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an “emerging growth company,” Tokai elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, Tokai will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that Tokai’s decision not to take advantage of the extended transition period is irrevocable. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company”, Tokai is not required to, among other things, (i) provide an auditor’s attestation report on its system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation.

Results of Operations

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes Tokai’s results of operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Change
	2016	2015	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	23,988	24,905	(917)
General and administrative	10,375	9,284	1,091
Total operating expenses	34,363	34,189	174
Loss from operations	(34,363)	(34,189)	(174)
Interest income and other income, net	141	119	22
Net loss	<u>\$ (34,222)</u>	<u>\$ (34,070)</u>	<u>\$ (152)</u>

[Table of Contents](#)*Research and Development Expenses*

	Nine Months Ended September 30,		Change
	2016	2015	
	(in thousands)		
Galeterone for prostate cancer	\$ 18,669	\$ 21,181	\$(2,512)
Other early-stage development programs and additional indications for galeterone	831	460	371
Unallocated research and development expenses	4,488	3,264	1,224
Total research and development expenses	<u>\$ 23,988</u>	<u>\$ 24,905</u>	<u>\$ (917)</u>

The decrease in research and development expenses associated with Tokai's galeterone for prostate cancer program for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was due primarily to decreased costs associated with the development of Tokai's AR-V7 clinical trial assay and companion diagnostic test of \$1.4 million and decreased manufacturing costs of \$0.9 million. Costs associated with the development of Tokai's AR-V7 clinical trial assay and companion diagnostic test for the nine months ended September 30, 2015 included a one-time fee paid for the exclusive right to have the circulating tumor cell enrichment technology used in the assay and related companion diagnostic test. The decrease in manufacturing costs primarily reflected a large purchase of raw materials during the nine months ended September 30, 2015 for use in manufacturing process optimization and validation studies required to support the submission of an NDA for galeterone. The increase in unallocated research and development expenses was primarily due to increased personnel related costs in Tokai's research and development function primarily related to severance costs as a result of the workforce reduction that occurred in the third quarter of 2016 as well as an impairment charge of \$0.2 million related to assets that had been used in the discontinued ARMOR3-SV trial.

General and Administrative Expenses

	Nine Months Ended September 30,		Change
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 5,421	\$ 4,095	\$ 1,326
Professional and consultant fees	3,337	3,603	(266)
Facility related and other	1,617	1,586	31
Total general and administrative expenses	<u>\$ 10,375</u>	<u>\$ 9,284</u>	<u>\$ 1,091</u>

The increase in personnel related costs for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily due to an increase in headcount in the general and administrative function associated with operating as a public company, including an increase in stock-based compensation expense of \$0.6 million as well as severance costs related to the workforce reduction that occurred in the third quarter of 2016. This was partially offset by cost savings as a result of this workforce reduction.

[Table of Contents](#)**Comparison of the Years Ended December 31, 2015 and 2014**

The following table summarizes Tokai's results of operations for the years ended December 31, 2015 and 2014:

	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2015</u>	<u>2014</u>	
	<u>(in thousands)</u>		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	32,638	14,577	18,061
General and administrative	12,623	8,885	3,738
Total operating expenses	<u>45,261</u>	<u>23,462</u>	<u>21,799</u>
Loss from operations	(45,261)	(23,462)	(21,799)
Interest and other income (expense), net	174	166	8
Net loss	<u>\$ (45,087)</u>	<u>\$ (23,296)</u>	<u>\$ (21,791)</u>

Research and Development Expenses

	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2015</u>	<u>2014</u>	
	<u>(in thousands)</u>		
Galeterone for prostate cancer	\$ 27,674	\$ 10,970	\$16,704
Other early-stage development programs and additional indications for galeterone	685	139	546
Unallocated research and development expenses	<u>4,279</u>	<u>3,468</u>	<u>811</u>
Total research and development expenses	<u>\$ 32,638</u>	<u>\$ 14,577</u>	<u>\$18,061</u>

The increase in research and development expenses associated with Tokai's galeterone for prostate cancer program for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to increased costs of clinical trials of \$10.4 million, costs associated with the development of its AR-V7 clinical trial assay and companion diagnostic test of \$3.9 million, and increased manufacturing costs of \$2.1 million. The increase in clinical trial costs was primarily related to the initiation of ARMOR3-SV during 2015, and costs associated with other clinical trials to support the submission of an NDA for galeterone. ARMOR3-SV costs included the purchase of Xtandi to be used in the trial for comparison against galeterone. Costs associated with the development of Tokai's AR-V7 clinical trial assay and companion diagnostic test included a fee paid for the exclusive right to have the circulating tumor cell enrichment technology used in the assay and companion diagnostic test. The increase in manufacturing costs was primarily due to a large purchase of raw materials during the year ended December 31, 2015 for use in the manufacture of registration lots and process validation activities required to support the submission of an NDA for galeterone. The increase in unallocated research and development expenses was primarily due to increased personnel related costs and facility costs as a result of increased headcount in Tokai's research and development function.

[Table of Contents](#)*General and Administrative Expenses*

	Year Ended December 31,		Change
	2015	2014	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 5,671	\$ 4,022	\$ 1,649
Professional and consultant fees	4,793	3,863	930
Facility related and other	2,159	1,000	1,159
Total general and administrative expenses	<u>\$ 12,623</u>	<u>\$ 8,885</u>	<u>\$ 3,738</u>

The increase in personnel related costs for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to increased headcount in Tokai's general and administrative function and an increase in overall compensation. Personnel related costs also increased in 2015 due to an increase in stock-based compensation expense of \$0.7 million related to additional employee stock options granted and a higher value of Tokai's common stock. Professional and consultant fees increased in 2015 compared to 2014 primarily due to an increase of \$2.0 million in patent costs and other fees associated with operating as a public company and costs associated with pre-commercialization activities, partially offset by a \$1.1 million fee incurred in 2014 in connection with strategic and financial advisory services that was not incurred in 2015. Facility related and other costs increased primarily due to increased insurance premiums, facility costs related to Tokai's new office lease and other costs related to Tokai's growth and operating as a public company.

Interest and Other Income (Expense), net

For the year ended December 31, 2015, interest and other income (expense), net consisted primarily of interest on investments. For the year ended December 31, 2014, interest and other income (expense), net consisted primarily of the collection of a loan receivable which had been fully reserved for in prior years.

Comparison of the Years Ended December 31, 2014 and 2013

The following table summarizes Tokai's results of operations for the years ended December 31, 2014 and 2013:

	Year Ended December 31,		Change
	2014	2013	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	14,577	12,201	2,376
General and administrative	8,885	3,548	5,337
Total operating expenses	<u>23,462</u>	<u>15,749</u>	<u>7,713</u>
Loss from operations	(23,462)	(15,749)	(7,713)
Interest and other income (expense), net	166	24	142
Net loss	<u>\$ (23,296)</u>	<u>\$ (15,725)</u>	<u>\$ (7,571)</u>

[Table of Contents](#)*Research and Development Expenses*

	Year Ended December 31,		Change
	2014	2013	
	(in thousands)		
Galeterone for prostate cancer	\$ 10,970	\$ 10,257	\$ 713
Other early-stage development programs and additional indications for galeterone	139	40	99
Unallocated research and development expenses	3,468	1,904	1,564
Total research and development expenses	<u>\$ 14,577</u>	<u>\$ 12,201</u>	<u>\$ 2,376</u>

The increase in research and development expenses associated with Tokai's galeterone for prostate cancer program for the year ended December 31, 2014 compared to the year ended December 31, 2013 was primarily due to increased costs of clinical trials of \$3.0 million and an increase of \$0.1 million in costs related to non-clinical studies to support Tokai's galeterone for prostate cancer program, partially offset by decreased manufacturing costs of \$2.3 million. The increase in clinical trial costs was due to an increased number of patients and sites in Tokai's ARMOR2 trial in the year ended December 31, 2014 as compared to the year ended December 31, 2013. The decrease in manufacturing costs was due to higher costs incurred in 2013 to manufacture galeterone for use in Tokai's ARMOR2 trial and in anticipation of Tokai's planned pivotal Phase 3 clinical trial of galeterone, including a large purchase of raw materials in 2013. Manufacturing costs in 2013 also included costs related to the technology transfer of Tokai's manufacturing process to a new vendor. The increase in unallocated research and development expenses was due to increased personnel related costs, including stock-based compensation expense, as a result of increased headcount in Tokai's research and development function.

General and Administrative Expenses

	Year Ended December 31,		Change
	2014	2013	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 4,022	\$ 1,731	\$ 2,291
Professional and consultant fees	3,863	1,392	2,471
Facility related and other	1,000	425	575
Total general and administrative expenses	<u>\$ 8,885</u>	<u>\$ 3,548</u>	<u>\$ 5,337</u>

The increase in personnel related costs for the year ended December 31, 2014 compared to the year ended December 31, 2013 was primarily due to stock-based compensation expense of \$2.1 million compared to \$0.2 million for the year ended December 31, 2013. The increase of \$1.9 million in stock-based compensation expense was related to additional employee stock options and a higher value of Tokai's common stock, as well as \$0.9 million recorded in the three months ended September 30, 2014 that was related to the vesting of a performance-based option grant upon the closing of Tokai's initial public offering in September 2014. Personnel related costs also increased as a result of increased headcount in Tokai's general and administrative function and an increase in overall compensation, partially offset by a decrease in personnel related costs due to severance paid to Tokai's former Chief Executive Officer in the year ended December 31, 2013. The increase in professional and consultant fees primarily consisted of a \$1.1 million fee payable to a financial advisor upon the closing of Tokai's initial public offering in connection with strategic and financial advisory services unrelated to the offering and an increase in accounting, public relations and patent fees associated with ongoing business activities and Tokai's preparations to operate as a public company as well as consulting fees for an external market research study that was conducted in 2014. Facility related and other expenses increased primarily due to increased insurance costs of \$0.2 million related to Tokai being a public company, increased facility costs of \$0.2 million to accommodate its additional employees and increased other taxes of \$0.1 million.

[Table of Contents](#)

Interest and Other Income (Expense), net

For the year ended December 31, 2014, interest and other income (expense), net consisted primarily of collection of a loan receivable from a former advisor, which had been fully reserved for in prior years.

Liquidity and Capital Resources

Since inception in March 2004, Tokai has not generated any revenue and has incurred recurring net losses. Tokai anticipates that it will continue to incur losses for at least the next several years. Tokai expects that it will need additional capital to fund its operations, which Tokai may obtain from additional financings, research funding, collaborations, contract and grant revenue or other sources.

To date, Tokai has funded its operations primarily through its initial public offering of its common stock, and prior to its initial public offering, private placements of its redeemable convertible preferred stock and convertible promissory notes. In September 2014, Tokai completed the initial public offering of its common stock through the issuance and sale of 6,480,000 shares of its common stock at a price to the public of \$15.00 per share, resulting in net proceeds of \$87.1 million after deducting underwriting discounts and commissions and offering expenses. In October 2014, Tokai issued and sold an additional 540,000 shares of its common stock as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock at the public offering price of \$15.00 per share and received additional net proceeds of \$7.5 million after deducting underwriting discounts and commissions.

Cash Flows

Comparison of the Nine Months Ended September 30, 2016 and 2015

As of September 30, 2016, Tokai's principal sources of liquidity were cash and investments of \$34.7 million.

The following table summarizes Tokai's sources and uses of cash and cash equivalents for each of the periods presented:

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Cash used in operating activities	\$ (29,210)	\$ (32,359)
Cash provided by (used in) investing activities	23,780	(40,194)
Cash provided by financing activities	37	465
Net decrease in cash and cash equivalents	<u>\$ (5,393)</u>	<u>\$ (72,088)</u>

Operating activities. During the nine months ended September 30, 2016, cash used in operating activities consisted of a net loss of \$34.2 million, partially offset by net non-cash charges of \$3.2 million and by net cash provided by changes in Tokai's operating assets and liabilities of \$1.9 million. Tokai's net non-cash charges during the period consisted primarily of stock-based compensation expense. Cash provided by changes in Tokai's operating assets and liabilities consisted primarily of a decrease in prepaid expenses and other current assets of \$1.7 million during the nine months ended September 30, 2016.

During the nine months ended September 30, 2015, cash used in operating activities consisted of a net loss of \$34.1 million, partially offset by net non-cash charges of \$1.9 million. Tokai's net non-cash charges during the period consisted almost entirely of stock-based compensation expense. Cash used in changes in Tokai's operating assets and liabilities consisted primarily of an increase in prepaid expenses and other current assets of \$1.5 million, partially offset by a net increase in accounts payable and accrued expenses of \$1.3 million.

[Table of Contents](#)

Tokai's prepaid expenses and other current assets and accounts payable and accrued expense balances have historically been affected by the volume of business and the timing of vendor invoicing and payments.

Investing activities. During the nine months ended September 30, 2016, proceeds from maturities of marketable securities were \$24.3 million and purchases of marketable securities were \$0.5 million. Tokai used a small amount of cash during the nine months ended September 30, 2016 related to purchases of property and equipment.

During the nine months ended September 30, 2015, net cash used in investing activities was primarily attributable to purchases of marketable securities of \$39.8 million and purchases of property and equipment of \$0.3 million primarily related to the purchase of lab equipment.

Financing activities. During the nine months ended September 30, 2016, net cash provided by financing activities was due to proceeds from the exercise of stock options. During the nine months ended September 30, 2015, net cash provided by financing activities was attributable to proceeds from the exercise of stock options and the repayment of notes receivable.

Comparison of the Years Ended December 31, 2015, 2014 and 2013

As of December 31, 2015, Tokai had cash and cash equivalents of \$24.0 million. Tokai invests its cash equivalents in money market accounts in order to preserve its principal.

The following table summarizes Tokai's sources and uses of cash for each of the periods presented:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Cash used in operating activities	\$ (41,236)	\$ (21,121)	\$ (15,476)
Cash used in investing activities	(40,510)	(175)	(53)
Cash provided by financing activities	513	94,799	35,591
Net increase (decrease) in cash and cash equivalents	<u>\$ (81,233)</u>	<u>\$ 73,503</u>	<u>\$ 20,062</u>

Operating activities. During the year ended December 31, 2015, cash used in operating activities consisted of Tokai's net loss of \$45.1 million, partially offset by net non-cash charges of \$2.8 million and by net cash provided by changes in Tokai's operating assets and liabilities of \$1.0 million. Tokai's net non-cash charges during the period consisted primarily of stock-based compensation expense. Cash provided by changes in Tokai's operating assets and liabilities consisted primarily of an increase in accounts payable and accrued expenses of \$1.9 million, partially offset by an increase in prepaid expenses and other current assets of \$1.0 million.

During the year ended December 31, 2014, cash used in operating activities was \$21.1 million, resulting from Tokai's net loss of \$23.3 million, partially offset by net non-cash charges of \$2.0 million and by net cash provided by changes in Tokai's operating assets and liabilities of \$0.2 million. Tokai's net non-cash charges during the period consisted primarily of stock-based compensation expense of \$2.1 million. Cash provided by changes in Tokai's operating assets and liabilities consisted primarily of a net increase in accounts payable and accrued expenses of \$2.0 million, partially offset by an increase in prepaid expenses and other current assets of \$1.8 million.

During the year ended December 31, 2013, cash used in operating activities was \$15.5 million, resulting from Tokai's net loss of \$15.7 million, partially offset by non-cash charges of \$0.2 million. Tokai's net non-cash charges during the year ended December 31, 2013 consisted primarily of stock-based compensation expense of \$0.2 million.

[Table of Contents](#)

Tokai's prepaid expenses and other current assets and accounts payable and accrued expense balances have historically been affected by the volume of business and the timing of vendor invoicing and payments.

Investing activities. During the year ended December 31, 2015, net cash used in investing activities was primarily attributable to purchases of marketable securities of \$39.9 million and purchases of property and equipment of \$0.6 million primarily related to the purchase of lab equipment and computer equipment.

Tokai used a small amount of cash during the years ended December 31, 2014 and 2013 related to purchases of property and equipment and to increase its restricted cash balance related to Tokai's corporate credit cards.

Financing activities. During the year ended December 31, 2015, net cash provided by financing activities was attributable to proceeds from the exercise of stock options and the repayment of notes receivable.

During the year ended December 31, 2014, net cash provided by financing activities was primarily due to proceeds, net of underwriting discounts and commissions, of \$97.9 million from Tokai's initial public offering, partially offset by payments of \$3.3 million of deferred offering costs related to its initial public offering that were paid during the period.

During the year ended December 31, 2013, net cash provided by financing activities was primarily due to net proceeds of \$35.4 million from the sale and issuance of Tokai's Series E redeemable convertible preferred stock.

Capital Requirements

Galeterone is still in clinical development. If, following a review of development options, Tokai determines to further develop galeterone, proceed with its ARDA program, or both, or acquire one or more other product candidates, Tokai anticipates that it will continue to incur significant expenses if and as it:

- conducts clinical trials of galeterone or any other product candidates in the future;
- identifies and develops compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation under its ARDA program;
- enters into agreements with third parties to manufacture galeterone or other product candidates;
- establishes a sales, marketing and distribution infrastructure to support the commercialization of its product candidates;
- maintains, expands and protects its intellectual property portfolio;
- continues its other research and development efforts;
- acquires or in-licenses additional compounds or technologies; and
- operates as a public company.

As of September 30, 2016, Tokai had cash and investments of \$34.7 million. In light of the discontinuation of the ARMOR3-SV trial and reduction in workforce that occurred in the third quarter of 2016 and assuming no new clinical efforts for galeterone or any other product candidate and that the Otic Transaction is not consummated, Tokai expects its cash and investments as of September 30, 2016 to be sufficient to fund operations for at least the next twelve months. Tokai is currently evaluating potential paths forward for galeterone and its ARDA program and is reviewing strategic alternatives. If Tokai determines to pursue an alternate strategy or engage in a strategic transaction, Tokai's future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by its management. If Tokai determines to further develop galeterone, proceeds with its ARDA program, or both, or

[Table of Contents](#)

acquire one or more other product candidates, Tokai will need to obtain substantial additional funding. Because of the significant uncertainty regarding Tokai's future plans, Tokai is not able to accurately predict the impact of a potential change on its business strategy and future funding requirements. If Tokai's cash and investments are not sufficient to fund its approved strategy and Tokai is unable to raise capital when needed or on acceptable terms, Tokai may be forced to delay, reduce, terminate or eliminate its product development programs and its commercialization efforts.

Tokai's future capital requirements will depend on many factors, including:

- Whether the Otic Transaction or another strategic alternative is consummated;
- its determination regarding potential paths forward for galeterone and its ARDA program;
- its analysis of the available unblinded data from ARMOR3-SV;
- the scope, progress and results of any additional clinical trials of galeterone that it decides to conduct;
- the timing and outcome of regulatory review of galeterone and of any other future product candidates;
- the cost of commercialization activities, including product sales, marketing, manufacturing and distribution, for galeterone and its future product candidates for which Tokai receives regulatory approval;
- the development of future product candidates, including its plans to seek to acquire or in-license additional compounds or technologies;
- revenue, if any, received from commercial sales of galeterone and any future product candidates, should any of its product candidates be approved by the FDA or a similar regulatory authority outside the United States;
- its ability to establish collaborations on favorable terms, if at all, particularly arrangements to develop, market and distribute galeterone and any future product candidates outside the United States; and
- the cost of preparing, filing and prosecuting patent applications, maintaining and enforcing its intellectual property rights and defending intellectual property-related claims.

Until such time, if ever, that Tokai can generate substantial product revenue, Tokai expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To this end, in October 2015, Tokai filed and the Securities and Exchange Commission, or the SEC, declared effective a shelf registration statement registering an aggregate of \$150 million in various equity and debt securities. Tokai has not issued or sold any securities under this registration statement. To the extent that Tokai raises additional capital through the sale of equity or convertible debt securities, the ownership interest of its stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of its common stockholders. Debt financing, if available, may involve agreements that require liens to be placed on Tokai's property and include covenants limiting or restricting Tokai's ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute its common stockholders' ownership interest. If Tokai raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, Tokai may have to relinquish valuable rights to its technologies, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to Tokai. If Tokai is unable to raise additional funds through equity or debt financings when needed, Tokai may be required to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market galeterone that Tokai would otherwise prefer to develop and market itself.

[Table of Contents](#)**Contractual Obligations and Commitments**

The following table summarizes Tokai's contractual obligations at September 30, 2016:

	Payments Due By Period			
	Total	Less than 1 year	1-3 Years	More Than 5 Years
Operating lease commitments (1)	\$1,468	\$ 140	\$ 1,328	\$ —
Total (2)(3)	<u>\$1,468</u>	<u>\$ 140</u>	<u>\$ 1,328</u>	<u>\$ —</u>

- (1) Tokai leases its headquarters in Boston, Massachusetts under an operating lease through July 2018.
- (2) Tokai is party to license agreements with University of Maryland, Baltimore and the Johns Hopkins University and a collaboration agreement with Qiagen under which it is obligated to make future payments upon the achievement of certain contingent milestones or pay royalties upon selling a commercial product or sublicensing the licensed technology. Tokai has not included these amounts in the table above as Tokai cannot estimate or predict when, or if, these amounts will become due. On October 28, 2016, Tokai agreed to terminate its project work plan with Qiagen. Upon making a final payment to Qiagen of \$1.1 million, Tokai will have no further financial obligations to Qiagen.
- (3) Tokai enters into contracts in the normal course of business with contract research organizations for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore Tokai believes that its non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

Tokai did not have during the periods presented, and Tokai does not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recently Issued Accounting Pronouncements

For information regarding recent accounting pronouncements, please refer to Note 2, "Summary of Significant Accounting Policies" appearing in Tokai's audited consolidated financial statements and Tokai's unaudited interim consolidated financial statements, included elsewhere in this proxy statement.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES
ABOUT TOKAI'S MARKET RISK**

As of September 30, 2016, Tokai's cash and investments consisted of cash, money market accounts, certificates of deposit and government bonds. The primary objectives of Tokai's investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Tokai's primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. Because of the short-term nature of the instruments in Tokai's portfolio, a sudden change in market interest rates would not be expected to have a material impact on its financial condition or results of operations.

**OTIC'S MANAGEMENT'S DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis of financial condition and results of operations should be read together with Otic's consolidated financial statements and the related notes appearing elsewhere in this proxy statement. In addition to historical information, the following discussion contains forward-looking statements that involve risks and uncertainties. Please see "Cautionary Statement Regarding Forward-Looking Information," beginning on page 64 of this proxy statement, for additional factors relating to such statements, and see "Risk Factors," beginning on page 29 of this proxy statement, for a discussion of certain risk factors applicable to Otic's business, financial condition and results of operation. Operating results are not necessarily indicative of results that may occur in future periods.

Overview

Otic is a clinical-stage, specialty pharmaceutical company focused on the acquisition and development of products for disorders of the ear, nose, and throat (ENT). Otic was founded in Israel in 2008. In 2015, Otic established U.S. operations and moved Otic's corporate headquarters to Southern California. Otic has two novel technologies that are initially being developed for conditions of the ear.

OP-01 is a foam-based technology. It is being developed by Otic with the intent to be used as a delivery vehicle for drugs which are to be placed into the ears, as well as the nasal and sinus cavities. OP-01 is currently being developed as an improved treatment option for acute otitis externa (AOE or "swimmers ear"), a common medical condition of the outer ear canal that globally affects tens of millions of adults and children every year. Otic has completed four clinical trials, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP-01 in 353 subjects, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP-01 that performed similarly to standard of care. Otic is now planning to modify the foam formulation of OP-01 to create a clinically differentiated, best-in-class product for AOE that is an improvement to the standard of care.

OP-02 is a surfactant-based technology. It was originally developed by Otodyne, Inc. and subsequently licensed to Otic in November 2015. OP-02 is currently being developed as a potential first-in-class treatment option for patients with otitis media (OM) and Eustachian tube dysfunction (ETD). OM and ETD are common medical conditions of the middle ear that globally affects more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice and it is the most frequent reason children are prescribed antibiotics and undergo surgery. OP-02 is a daily nasal spray, designed to improve and maintain the Eustachian tube's ability to drain and ventilate the middle ear. Otic is planning to initiate multiple phase 1 clinical studies of OP-02 in 2017 to explore the safety and tolerability of OP-02, as well as explore how OP-02 affects the Eustachian tube (pharmacodynamics). These phase 1 studies will evaluate single and repeated intranasal doses of OP-02 in adults. Upon completion of these studies, Otic expects that its initial phase 2 studies of OP-02 will focus on prevention of acute, recurrent, and chronic OM in children.

Otic has no products approved for commercial sale. Otic has not generated any revenue and Otic has incurred significant operating losses in each year since Otic's inception in 2008. Substantially all of Otic's operating losses resulted from expenses incurred in connection with Otic's research and development programs and from general and administrative costs associated with Otic's operations. Otic will need to expend substantial resources and Otic expects to continue to generate operating losses for the foreseeable future as Otic continues to pursue Otic's research and development programs for the treatment of AOE and OM.

Otic is the subject to a number of risks and uncertainties similar to those of other life science companies developing new products, including, among others, the risks related to the necessity to obtain adequate additional financing, to successfully develop product candidates, to obtain regulatory approval of product candidates, to comply with government regulations, to successfully commercialize potential products, to the protection of proprietary technology and to the dependence on key individuals. Furthermore, due to the uncertainty of pharmaceutical product development, Otic may never achieve future revenue through product sales, licensing or partnership agreements.

[Table of Contents](#)

From inception through September 30, 2016, Otic has raised net cash proceeds of approximately \$14.4 million from private investors through both equity and convertible debt financing to fund operating activities. As of September 30, 2016, Otic had an accumulated deficit of \$12.9 million and \$2.4 million of cash and cash equivalents. Based upon current operating plans, Otic expects the proceeds from the Equity Financing, along with net cash held by each of Tokai and Otic upon consummation of the Otic Transaction, will be sufficient to fund operations into the second half of 2018. Cash requirements may vary materially from those now planned because of changes in the focus and direction of Otic's research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after Otic exhausts its current cash resources and to continue Otic's long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be obtained, or if obtained, what the terms thereof may be, or that any amount that Otic is able to raise will be adequate to support Otic's working capital requirements until Otic achieves profitable operations.

Recent Developments

On December 21, 2016, Otic entered into a Share Purchase Agreement pursuant to which Tokai will acquire all of the outstanding equity of Otic. Subject to the terms and conditions of the Share Purchase Agreement, at the closing of the transaction, Tokai will be renamed "OticPharma, Inc."

Following the closing of the Otic Transaction, the stockholders of Otic are expected to own approximately 60% of the combined company and the stockholders of Tokai are expected to own approximately 40% of the combined company. The transaction has been approved by the board of directors of both companies and by the shareholders of Otic. The transaction is expected to close in the first half of 2017, subject to the approval of the stockholders of Tokai and other customary closing conditions, as detailed in this proxy statement.

In connection with the transaction, Otic will be deemed to be the accounting acquirer and therefore the transaction will be treated as a reverse acquisition because (i) Otic security holders are expected to own approximately 60% of the voting interests of the combined company immediately following the closing of the transaction; (ii) directors appointed by Otic will hold a majority of the board seats in the combined company; and (iii) Otic management will hold all key positions in the management of the combined company. Otic is expected to incur additional general and administrative expenses as it complies with the exchange listing and SEC requirements. In addition, Otic will be treated as the predecessor company for financial reporting purposes going forward with a fiscal year ending December 31.

Research and Development Expenses

Otic's research and development expenses consist primarily of development costs for Otic's two novel technologies that are initially being developed for conditions of the ear, including preclinical and clinical development costs. Otic contracts with clinical research organizations to manage clinical trials under agreed upon budgets for each study, with oversight by Otic's clinical function. Research and development costs are expensed as incurred. Otic expects research and development expenses to increase as Otic expands the research and development function in preparation for additional formulation of OP-01 and the initiation of phase 1 clinical studies in OP-02.

Otic's research and development expenses consist primarily of:

- external expenses paid to clinical trial sites, contract research organizations, laboratories, database software and consultants that conduct clinical trials;
- expenses related to development and the production of nonclinical and clinical trial supplies, including fees paid to contract manufacturers;
- expenses related to preclinical studies;

Table of Contents

- expenses related to compliance with drug development regulatory requirements;
- other allocated expenses, including costs associated with obtaining and maintaining Otic's patent portfolio; and
- costs of all employees and consultants engaged in research and development activities.

Royalty-bearing grants from the OCS to fund approved research and development projects are recognized when Otic is entitled to such grants, on the basis of the costs incurred and applied as a reduction of research and development expenses.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs associated with general management, professional fees for accounting, auditing, consulting and legal services, and general overhead expenses.

Otic expects general and administrative expenses to increase in the future as Otic expands its corporate function and incurs costs in preparation of becoming a public company and maintaining compliance with exchange listing and SEC requirements. Otic expects these potential increased costs to include management costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and expenses associated with investor relations.

Critical Accounting Policies and Significant Judgments and Estimates

Otic's management's discussion and analysis of its financial condition and results of operations are based on its financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires Otic to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities at the date of the financial statements. On an ongoing basis, Otic evaluates its estimates and judgments, including those related to accrued research and development expenses. Otic bases its estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Otic's significant accounting policies are described in more detail in the notes to its financial statements appearing elsewhere in this proxy statement.

Results of Operations

From inception through September 30, 2016, Otic has raised net cash proceeds of approximately \$14.4 million from private investors through both equity and convertible debt financing to fund operating activities. As of September 30, 2016, Otic had an accumulated deficit of \$12.9 million and \$2.4 million of cash and cash equivalents. Based upon current operating plans, Otic expects the proceeds from the Equity Financing, along with net cash held by each of Tokai and Otic upon consummation of the Otic Transaction, will be sufficient to fund operations into the second half of 2018. Cash requirements may vary materially from those now planned because of changes in the focus and direction of Otic's research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after Otic exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be obtained, or if obtained, what the terms thereof may be, or that any amount that Otic is able to raise will be adequate to support Otic's working capital requirements until it achieves profitable operations.

[Table of Contents](#)

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes Otic's results of operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Change
	2016	2015	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development expenses, net	2,335	1,521	814
General and administrative expenses	1,326	566	760
Total operating expenses	3,661	2,087	1,574
Loss from operations	(3,661)	(2,087)	(1,574)
Interest income (expense), net	(479)	17	(496)
Net loss	<u>\$ (4,140)</u>	<u>\$ (2,070)</u>	<u>\$(2,070)</u>

Research and Development Expenses, net

Research and development expenses, net by development program for the nine months ended September 30, 2016 and 2015 were as follows:

	Nine Months Ended September 30,		Change
	2016	2015	
	(in thousands)		
OP-01 for Acute Otitis Externa	\$ 884	\$ 1,462	\$ (578)
OP-02 for Otitis Media	1,451	59	1,392
Total research and development expenses, net	<u>\$ 2,335</u>	<u>\$ 1,521</u>	<u>\$ 814</u>

Research and development expenses, net increased by \$814,000 for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. The increase is primarily due to a new development program, OP-02 for otitis media, that was initiated in the fourth quarter of 2015, offset by decreased spending towards the OP-01 acute otitis externa program.

Otic expects research and development expenses to increase as Otic expands the research and development function in preparation for the initiation of phase 1 clinical studies in OP-02.

Grant income applied as a deduction from research and development expenses was approximately \$39,000 and \$5,000 for the nine months ended September 30, 2016 and 2015, respectively.

Table of Contents*General and Administrative Expenses*

General and administrative expenses for the nine months ended September 30, 2016 and 2015 were as follows:

	Nine Months Ended September 30,		Change
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 929	\$ 100	\$ 829
Professional and consultant fees	144	411	(267)
Facility related and other	253	55	198
Total general and administrative expenses	<u>\$ 1,326</u>	<u>\$ 566</u>	<u>\$ 760</u>

General and administrative expenses increased by \$760,000 for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. The increase was primarily due to an increase in personnel-related and facilities costs resulting from the establishment of U.S. operations in a new Southern California-based corporate headquarters in the fourth quarter of 2015. This was partially offset by decreased spending on professional and consultant fees.

Otic expects general and administrative expenses to increase in the future as Otic expands Otic's corporate function and incur costs in preparation of becoming a public company and maintaining compliance with exchange listing and SEC requirements. Otic expects these potential increased costs to include management costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and expenses associated with investor relations.

Other Income (Expense), net

For the nine months ended September 30, 2016, other income (expense), net of \$479,000 consisted primarily of non-operating expense of \$517,000 related to the fair value of convertible debt in excess of proceeds. For the nine months ended September 30, 2015, other income (expense), net of \$17,000 consisted primarily of interest income on investments.

Comparison of the Years Ended December 31, 2015 and 2014*Results of Operations*

The following table summarizes Otic's results of operations for the years ended December 31, 2015 and 2014:

	Year Ended December 31,		Change
	2015	2014	
	(in thousands)		
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	2,774	946	1,828
General and administrative	1,415	208	1,207
Total operating expenses	<u>4,189</u>	<u>1,154</u>	<u>3,035</u>
Loss from operations	(4,189)	(1,154)	(3,035)
Interest and other income, net	(25)	(6)	(19)
Net loss	<u>\$ (4,214)</u>	<u>\$ (1,160)</u>	<u>\$ (3,054)</u>

Table of Contents

Research and Development Expenses

Research and development expenses by development program for the fiscal year ended December 31, 2015 and 2014 were as follows (in thousands):

	Year Ended December 31,		Change
	2015	2014	
	(in thousands)		
OP-01 for Acute Otitis Externa	\$ 1,891	\$ 946	\$ 945
OP-02 for Otitis Media	883	—	883
Total research and development expenses	<u>\$ 2,774</u>	<u>\$ 946</u>	<u>\$ 1,828</u>

Research and development expenses increased by \$1.8 million for the fiscal year ended December 31, 2015 compared to the fiscal year ended December 31, 2014. The increase is primarily due to costs incurred for phase 3 clinical trials planning, including manufacturing costs, for the OP-01 acute otitis externa development program and the initiation of a new development program, OP-02 for otitis media, which commenced in the fourth quarter of 2015.

In 2016, Otic stopped further development of the first-generation, antibiotic-only product and began development of a second-generation formulation of OP-01 which will include both an antibiotic plus a second active ingredient to address ear pain.

General and Administrative Expenses

	Year Ended December 31,		Change
	2015	2014	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 531	\$ 13	\$ 518
Professional and consultant fees	709	137	572
Facility related and other	175	58	117
Total general and administrative expenses	<u>\$ 1,415</u>	<u>\$ 208</u>	<u>\$ 1,207</u>

General and administrative expenses increased by \$1.2 million for the fiscal year ended December 31, 2015 compared to the fiscal year ended December 31, 2014. The increase was primarily related to an increase in personnel-related and facilities costs resulting from the establishment of U.S. operations in a new Southern California-based corporate headquarters in the fourth quarter of 2015. In addition, professional and consultant fees increased due to costs related to commercial assessment of OP-01 in acute otitis externa.

Other Income (Expense), net

For the years ended December 31, 2015 and 2014, other income (expense), net consisted primarily of interest expense.

Liquidity and Capital Resources

Otic has experienced net losses since inception and expects to continue to generate losses for the foreseeable future as Otic continues to pursue development programs for the treatment of acute otitis externa and otitis media. Otic has no products approved for commercial sale and have not generated revenue since Otic's inception in 2008. Furthermore, due to the uncertainty of pharmaceutical product development, Otic may never achieve revenue in the future through product sales, licensing or partnership agreements.

From inception through September 30, 2016, Otic has raised net cash proceeds of approximately \$14.4 million from private investors through both equity and convertible debt financing to fund operating

[Table of Contents](#)

activities. As of September 30, 2016, Otic had an accumulated deficit of \$12.9 million and \$2.4 million of cash and cash equivalents. Based upon current operating plans, Otic expects the proceeds from the Equity Financing, along with net cash held by each of Tokai and Otic upon consummation of the Otic Transaction, will be sufficient to fund operations into the second half of 2018. Cash requirements may vary materially from those now planned because of changes in the focus and direction of Otic's research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after Otic exhausts current cash resources and to continue Otic's long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be obtained, or if obtained, what the terms thereof may be, or that any amount that Otic raises will be adequate to support Otic's working capital requirements until Otic achieves profitable operations.

Cash Flows

Comparison of the Nine Months Ended September 30, 2016 and 2015

As of September 30, 2016, Otic's principal source of liquidity was cash and cash equivalents of \$2.4 million.

The following table summarizes Otic's sources and uses of cash and cash equivalents for each of the periods presented:

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Cash used in operating activities	\$ (3,641)	\$ (1,724)
Cash used in investing activities	(12)	(7)
Cash provided by financing activities	2,930	1,903
Net increase (decrease) in cash and cash equivalents	<u>\$ (723)</u>	<u>\$ 172</u>

Operating activities

During the nine months ended September 30, 2016, cash used in operating activities of \$3.6 million consisted of a net loss of \$4.1 million and net cash used by changes in Otic's operating assets and liabilities of \$176,000, partially offset by net non-cash charges of \$675,000. Otic's net non-cash charges during the period consisted primarily of the fair value of debt issued in excess of proceeds received, stock-based compensation expense and depreciation. Cash used in changes in Otic's operating assets and liabilities consisted primarily of a net decrease in accounts payable and other current liabilities of \$218,000 during the nine months ended September 30, 2016.

During the nine months ended September 30, 2015, cash used in operating activities of \$1.7 million consisted of a net loss of \$2.1 million, partially offset by net non-cash charges of \$38,000 and by net cash provided by changes in Otic's operating assets and liabilities of \$308,000. Otic's net non-cash charges during the period consisted of stock-based compensation expense and depreciation. Cash provided by changes in Otic's operating assets and liabilities consisted primarily of an increase in accounts payable and other current liabilities of \$340,000 during the nine months ended September 30, 2015.

Investing activities

During the nine months ended September 30, 2016, net cash used in investing activities of \$12,000 was primarily attributed to the purchase of property and equipment related to the opening of Otic's new corporate headquarters in Southern California.

[Table of Contents](#)

During the nine months ended September 30, 2015, net cash used in investing activities of \$7,000 was attributed to the purchase of property and equipment.

Financing activities

During the nine months ended September 30, 2016, net cash provided by financing activities of \$2.9 million was primarily attributed to proceeds from a convertible loan.

During the nine months ended September 30, 2015, net cash provided by financing activities of \$1.9 million was primarily attributed to proceeds from the sale of Series C preferred shares.

Comparison of the Years Ended December 31, 2015 and 2014

As of December 31, 2015, Otic had cash and cash equivalents of \$3.1 million.

The following table summarizes Otic's sources and uses of cash for each of the periods presented:

	Year Ended	
	December 31,	
	2015	2014
Cash used in operating activities	\$(3,698)	\$ (912)
Cash used in investing activities	(62)	—
Cash provided by financing activities	<u>5,290</u>	<u>1,500</u>
Net increase in cash and cash equivalents	<u>\$ 1,530</u>	<u>\$ 588</u>

Operating activities

During the year ended December 31, 2015, cash used in operating activities of \$3.7 million consisted of Otic's net loss of \$4.2 million, partially offset by net non-cash charges of \$215,000 and by net cash provided by changes in Otic's operating assets and liabilities of \$301,000. Otic's net non-cash charges during the period consisted primarily of stock-based compensation expense and stock issued for licensing fees. Cash provided by changes in Otic's operating assets and liabilities consisted primarily of an increase in accounts payable and other current liabilities of \$382,000, partially offset by an increase in other current assets of \$81,000.

During the year ended December 31, 2014, cash used in operating activities was \$912,000, resulting from Otic's net loss of \$1.2 million, partially offset by net non-cash charges of \$90,000 and by net cash provided by changes in Otic's operating assets and liabilities of \$158,000. Otic's net non-cash charges during the period consisted primarily of stock-based compensation expense and depreciation. Cash provided by changes in Otic's operating assets and liabilities consisted primarily of a decrease in other current assets of \$149,000, combined with a net increase in accounts payable and other current liabilities of \$9,000.

Investing activities

During the year ended December 31, 2015, net cash used in investing activities of \$62,000 was primarily attributed to the purchase of property and equipment related to the opening of Otic's new Southern California headquarters in the fourth quarter of 2015.

During the year ended December 31, 2014, no cash was used in investing activities.

Financing activities

During the year ended December 31, 2015, net cash provided by financing activities of \$5.3 million was attributed to proceeds from the sale of Series C preferred shares.

[Table of Contents](#)

During the year ended December 31, 2014, net cash provided by financing activities of \$1.5 million was primarily due to proceeds from the sale of Series B preferred shares.

Contractual Obligations and Commitments

The following table summarizes Otic's contractual obligations as of September 30, 2016:

	Payments Due By Period				
	Total	Less than 1 year	1- 3 Years	3- 5 Years	More Than 5 Years
Operating lease commitments (1)	\$ 324	\$ 171	\$ 153	\$ —	\$ —
Total (2)(3)(4)	<u>\$ 324</u>	<u>\$ 171</u>	<u>\$ 153</u>	<u>\$ —</u>	<u>\$ —</u>

- (1) Operating lease commitments are comprised of the following:
- An office lease for Otic Pharma, Ltd. which is located in Rehovot, Israel. The office space was leased under an operating lease through November 2016. The lease was not extended beyond November 2016.
 - An office lease for Otic Pharma, Inc., Otic's subsidiary, which is located in Irvine, California in a 5,113 square-foot office space. The Irvine office is leased under an operating lease through September 2018.
 - A vehicle lease for employees located in the Rehovot, Israel office. The vehicle lease was canceled effective December 2016.
- (2) As of December 31, 2015, Otic received loans in the amount of approximately \$537,000 from the OCS designated for Otic's investments in research and development. The loans are linked to the U.S. dollar and bear annual interest of LIBOR. The loans are to be repaid out of royalties from sales of the products developed by Otic from their investments in research and development.
- (3) In November 2015, the Otic Pharma, Inc., Otic's subsidiary, entered into an Exclusive License Agreement with Scientific Development and Research Inc. and Otodyne Inc. (the "Licensors"), according to which the Licensors shall provide the License Technology, as defined in the Exclusive License Agreement, to the subsidiary. In return for the Exclusive License Agreement, Otic Pharma, Inc. paid to the Licensors a license fee in a total amount of \$600,000, and Otic issued to the Licensors 88,024 Ordinary Shares NIS 0.01 par value each. In addition, Otic Pharma, Inc. paid an additional amount of \$100,000 as a Technology Transfer Fee, as defined in the Exclusive License Agreement, and future milestones and royalty payments, as defined and detailed in the Exclusive License Agreement.
- (4) On July 11, 2016, OrbiMed Israel Partners Limited Partnership and Peregrine Management II Ltd. provided Otic with a convertible bridge financing in the aggregate amount of \$2,930,000 (the "Bridge Financing Amount"), pursuant to a Bridge Financing Agreement, dated July 11, 2016 (the "Bridge Financing Agreement"). Under the terms of the Bridge Financing Agreement, other than upon occurrence of an Event of Default (as defined in the Bridge Financing Agreement), Otic is not required to repay the Bridge Financing Amount or any portion in cash. The Bridge Financing Agreement further provides that upon a Deemed Liquidation (as defined in Otic's Articles of Association), the Bridge Financing Amount is convertible into 606,845 Preferred C Shares of Otic at a price per share representing 85% of the Preferred C Shares' original issue price. As such, conversion will occur upon closing of the Otic Transaction pursuant to the terms of the Bridge Financing Agreement.

Off-Balance Sheet Arrangements

Otic did not have during the periods presented, and Otic does not currently have, any off-balance sheet arrangements, as defined under SEC rules.

[Table of Contents](#)

Management Outlook

Otic has experienced net losses since inception and Otic expects to continue to generate losses for the foreseeable future as Otic continues to pursue its development programs in acute otitis externa and otitis media. Otic expects that the proceeds from the Equity Financing, along with net cash held by each of Tokai and Otic upon consummation of the Otic Transaction, will be sufficient to fund its operations into the second half of 2018. Otic may seek to raise additional capital and may do so at any time through various financing alternatives, including licensing or sale of drug candidates or selling shares of stock.

Recently Issued Accounting Pronouncements

For information regarding recent accounting pronouncements, please refer to Note 2, *Summary of Significant Accounting Policies*, within Otic's unaudited consolidated financial statements, beginning on page F-59 of this proxy statement.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES
ABOUT OTIC'S MARKET RISK**

Interest Rate Risk

As of September 30, 2016, Otic's cash and cash equivalents consisted of cash and money market accounts. The primary objective of Otic's investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Otic's primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. Because all of Otic's cash is held in either cash or money market accounts, a sudden change in market interest rates would not be expected to have a material impact on its financial condition or results of operations.

Foreign Exchange Rate Risk

Otic operates internationally and is exposed to foreign exchange risk arising from various exposures, primarily with respect to the Euro. Historically, Otic's clinical trials have been conducted in Europe. To manage foreign exchange risk, Otic maintains foreign currency cash balances to cover anticipated future purchases of materials and services in foreign currencies. The effect of an increase or decrease in the USD/Euro exchange rate would have an immaterial effect in profit or loss.

Effects of Inflation

Otic believes the impact of inflation and changing prices on operations has been minimal during the past three years.

**EXECUTIVE OFFICERS AND DIRECTORS FOLLOWING
THE OTIC TRANSACTION**

Executive Officers and Directors

Termination of Current Executive Officers of Tokai

The employment of the current executive officers of Tokai is expected to be terminated upon the consummation of the Otic Transaction. However, if necessary, certain executive officers may provide transitional services to the combined company following the consummation of the Otic Transaction.

Executive Officers and Directors of the Combined Company Following the Consummation of the Otic Transaction

The Share Purchase Agreement provides that promptly after closing of the Otic Transaction, Tokai shall take all action necessary to cause either (i) the resignation of three members of the existing Tokai board of directors or (ii) the resignation of four members of the existing Tokai board of directors and the appointment of one person designated by Otic to the Tokai board of directors.

The combined company's board of directors will initially be fixed at seven members, consisting of (i) three members designated by Tokai, namely _____, _____ and _____ and (ii) four members designated by Otic, namely Keith A. Katkin as Chairman, Gregory J. Flesher, Gary A. Lyons, and Erez Chimovits. The staggered structure of the current Tokai board of directors will remain in place for the combined company following the consummation of the Otic Transaction.

The following table lists the names and ages as of January 13, 2017, and positions of the individuals who are expected to serve as executive officers and directors of the combined company upon consummation of the Otic Transaction:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<i>Executive Officers</i>		
Gregory J. Flesher	46	Chief Executive Officer and Director
Christine G. Ocampo	44	Chief Financial and Compliance Officer
Dr. Catherine C. Turkel	56	Chief Development Officer
<i>Non-Employee Directors</i>		
Keith A. Katkin	45	Chairman of the Board
Gary A. Lyons	65	Director
Erez Chimovits	53	Director
		Director
		Director

Executive Officers

Gregory J. Flesher. Mr. Flesher was appointed Chief Executive Officer of Otic in July 2015. Mr. Flesher has over 20 years of pharmaceutical industry experience. Prior to joining Otic, Mr. Flesher held positions as Senior Vice President and Chief Business Officer, Vice President of Business Development, and Senior Director of Commercial Strategy at Avanir Pharmaceuticals, Inc. from 2006 to 2015. Mr. Flesher also held positions as Director of Hepatology Sales and Director of Pulmonary Marketing from 2002 to 2006 at InterMune, Inc., as well commercial roles in both the Oncology and Nephrology business units at Amgen, Inc. from 1999 to 2002. Mr. Flesher began his industry career at Eli Lilly and Company where he held positions in both clinical development and global marketing from 1995 to 1998. During his industry tenure, Mr. Flesher has

[Table of Contents](#)

participated in several drug development programs resulting in multiple product approvals and successful launches in the U.S. and Europe. Mr. Flesher earned his Bachelor of Science in Biology from Purdue University and studied Biochemistry and Molecular Biology at Indiana University School of Medicine. Otic believes Mr. Flesher is qualified to serve on the combined company's board of directors due to his service prior to closing of the Otic Transaction as Chief Executive Officer of Otic and his tenure in the industry, which includes a number of senior leadership roles at other biopharmaceutical companies.

Christine G. Ocampo, CPA. Ms. Ocampo joined Otic in September 2015 and currently serves as Senior Vice President and Chief Financial Officer. Ms. Ocampo has over 20 years of accounting and finance experience, including over 11 years as the head of Finance for publicly-traded companies in the healthcare industry. Prior to joining Otic, Ms. Ocampo served in the roles of Vice President of Finance, Chief Accounting Officer and Vice President of Finance, Chief Compliance Officer and Secretary from 2006 to 2015 at Avanir Pharmaceuticals, Inc. Prior to Avanir, Ms. Ocampo served as Senior Vice President, Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary and Vice President, Corporate Controller of Cardiogenesis Corporation (now CryoLife, Inc.), a publicly-traded medical device company, from 2001 to 2006. Prior to Cardiogenesis, Ms. Ocampo held a management role in Finance at Mills-Peninsula Health Systems in Burlingame, California, and served as an auditor for Ernst & Young LLP. Ms. Ocampo graduated with a Bachelor of Arts in Accounting from Seattle University and became a licensed Certified Public Accountant in 1996.

Catherine C. Turkel, PharmD, MBA, PhD. Dr. Turkel joined Otic in November 2015 and currently serves as Senior Vice President and Chief Development Officer. She is responsible for leading Otic's preclinical, clinical, regulatory, quality assurance and CMC development functions. Dr. Turkel has more than 30 years of combined clinical practice and drug development experience. Dr. Turkel has successfully led global development project teams resulting in multiple registrations of new drug treatments around the world. Prior to Otic, Dr. Turkel held several R&D leadership positions at Allergan, Inc., including Vice President of Clinical Development for Neurology, Urology, and Pain, Vice President of Global Medical Affairs, and other positions between 1998 and 2015. Prior to Allergan, Dr. Turkel was Director of Drug Development, Regulatory Affairs and Data Management at Cypros Pharmaceuticals from 1995 to 1998. Dr. Turkel industry tenure also includes past positions at IVAC Corporation, California Clinical Trials, and Siemens Infusion Systems as well as many years as a hospital based critical care pharmacist. Dr. Turkel holds a Doctor of Pharmacy from the University of the Pacific, an MBA from the University of California, Irvine, and a Doctor of Philosophy in Business from Capella University.

Non-Employee Directors

Keith A. Katkin. Mr. Katkin joined Otic Pharma as Chairman of the Board of Directors in November 2015. Mr. Katkin is currently a member of the board of directors of Avanir Pharmaceuticals, Inc., a position he has held since March of 2007. Mr. Katkin served as the President and Chief Executive Officer of Avanir Pharmaceuticals from 2007 through the company's acquisition by Otsuka pharmaceuticals in 2015. Avanir Pharmaceuticals focused on the development, acquisition, and commercialization of therapeutic products for the treatment of central nervous system disorders. Mr. Katkin was appointed by the Avanir Pharmaceuticals board of directors to lead Avanir through its turnaround and restructuring, and his successful implementation of a new corporate strategy increased market capitalization from \$50 million to \$3.5 billion and grew the team from 17 employees to over 500. Prior to serving as President and CEO, Mr. Katkin was the Senior Vice President of Sales and Marketing at Avanir. Prior to joining Avanir, Mr. Katkin served as the Vice President, Commercial Development for Peninsula Pharmaceuticals, playing a key role in the concurrent initial public offering and ultimate sale of the company to Johnson and Johnson. Additionally, Mr. Katkin's employment experience includes leadership roles at InterMune, Amgen and Abbott Laboratories. In addition to the board of directors of Otic Pharma and Avanir, Mr. Katkin is currently a member of the board of directors of CoverMyMeds, Rigel Pharmaceuticals, Inc., MC10 and the Brain Injury Association of America. Mr. Katkin has an M.B.A. from the Anderson School at UCLA and earned his B.S. in Business and Accounting from Indiana University. Mr. Katkin became a licensed certified public accountant in 1995. Otic believes Mr. Katkin is qualified to serve on the

[Table of Contents](#)

combined company's board of directors due to his service prior to closing of the Otic Transaction as Chairman of the Board of Directors of Otic and his years of experience in and extensive knowledge of the industry.

Gary A. Lyons. Mr. Lyons has more than 35 years of industry experience. Mr. Lyons is currently a member of the Board of Directors of Neurocrine Biosciences, Inc., a position he has held since 1993. Mr. Lyons joined Neurocrine in 1993 as Chief Executive Officer until 2008. Mr. Lyons also serves on the board of directors of Vical, Inc., Cytospor Therapeutics, Inc., and is the Chairman of the Board of Directors for Rigel Pharmaceuticals and Retrophin Inc. He previously served on the board of directors of PDL BioPharma, Inc. Facet Biotech Corporation following Facet's spin-off from PDL, until Facet's acquisition by Abbott Laboratories in April 2010. Mr. Lyons also served on the board of directors of Poniard Pharmaceuticals, Inc., NeurogesX, Inc. and KaloBios Pharmaceuticals, Inc., each a biopharmaceutical company. From 1983 to 1993, he held a number of management positions at Genentech, including Vice President of Business Development and Vice President of Sales, and also served as a member of Genentech's Executive Committee. Mr. Lyons was responsible for international licensing, acquisitions and partnering for Genentech's Corporate Venture Program and had operating responsibility for two subsidiaries, Genentech Canada, Inc. and Genentech Limited (Japan). He holds a B.S. in Marine Biology from the University of New Hampshire and an M.B.A. from Northwestern University's J.L. Kellogg Graduate School of Management. Otic believes Mr. Lyons is qualified to serve on the combined company's board of directors due to his depth of knowledge of the industry and his many years of experience serving on the board of directors of biopharmaceutical companies.

Erez Chimovits, M.Sc., MBA. Mr. Chimovits is a Senior Managing Director at OrbiMed. He has more than fourteen years of operational experience, including ten years of senior managerial experience in public companies. Prior to joining OrbiMed, he was the Chief Executive Officer of NasVax (TASE: NSVX). NasVax acquired Protea and struck key agreements with GlaxoSmithKline and Novartis. Previously, Mr. Chimovits spent more than seven years with Compugen (Nasdaq: CGEN), as President, Compugen USA Inc. and Executive Vice President, Commercial Operations. While at Compugen, he had P&L responsibility for more than 100 people and led multiple transactions including J&J, Novartis, Teva, Abbott, Medarex and others. Mr. Chimovits earned his M.B.A., M.Sc. in Microbiology and his B.Sc. from Tel Aviv University. Otic believes Mr. Chimovits is qualified to serve on the combined company's board of directors due to his vast operational and managerial experience in the biopharmaceutical industry, much of which took place in public companies.

In accordance with Tokai's certificate of incorporation and by-laws, the Tokai board of directors is divided into three classes, with members of each class holding office for staggered three-year terms. There are currently three Class I directors (Jodie P. Morrison, Cheryl L. Cohen and Joseph A. Yanchik, III), whose terms expire at the 2018 annual meeting of stockholders; one Class II director (David A. Kessler), whose term expires at the 2019 annual meeting of stockholders; and two Class III directors (Seth L. Harrison and Stephen Buckley Jr.), whose terms expire at the 2017 annual meeting of stockholders (in all cases subject to the election and qualification of their successors or to their earlier death, resignation or removal). Drs. Harrison and Kessler were elected as directors pursuant to a stockholders agreement that Tokai entered into with the holders of Tokai preferred stock that terminated upon the closing of Tokai's initial public offering. Timothy J. Barberich, who was elected as a Class II director of Tokai at Tokai's 2016 annual meeting, resigned from Tokai's board of directors effective as of October 10, 2016.

The director classes for Tokai are currently as follows:

- Class I directors (term ending in 2018): Cheryl L. Cohen, Jodie P. Morrison and Joseph A. Yanchik, III;
- Class II directors (term ending in 2019): David A. Kessler.; and
- Class III director (term ending in 2017): Seth L. Harrison and Stephen Buckley, Jr.

[Table of Contents](#)

The combined company's board of directors will initially be fixed at seven members, consisting of (i) four members designated by Otic: Keith A. Katkin as Chairman, Gregory J. Flesher, Gary A. Lyons and Erez Chimovits and (ii) three board members designated by Tokai, which may include existing board members and up to one new member designated by Tokai.

Pursuant to the terms of the Share Purchase Agreement, it is anticipated that these directors will be appointed to the three staggered director classes of the combined company's board of directors as follows:

- Class I directors (term ending 2018):
- Class II directors (term ending 2019):
- Class III directors (term ending 2017):

Family Relationships

There are no family relationships among any of the current Tokai directors and executive officers, and there are no family relationships, among any of the proposed combined company directors and officers. There are no arrangements or understandings with another person under which the directors and executive officers of the combined company was or is to be selected as a director or executive officer. Additionally, no director or executive officer of the combined company is involved in legal proceedings which require disclosure under Item 401 of Regulation S-K.

Director Independence

Rule 5605 of the NASDAQ Listing Rules requires a majority of a listed company's board of directors to be comprised of independent directors. In addition, the NASDAQ Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Rule 5605(a)(2) of the NASDAQ Listing Rules, a director will only qualify as an "independent director" if, in the opinion of Tokai's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, Tokai's board of directors believes that each of the directors of the combined company, with the exception of Mr. Flesher, will be an "independent director" as defined under Rule 5605(a)(2) of the NASDAQ Listing Rules following the consummation of the Otic Transaction.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT OF TOKAI

The following table presents information as to the beneficial ownership of Tokai common stock as of December 31, 2016 for:

- each person, or group of affiliated persons, known by Tokai to beneficially own more than 5% of Tokai common stock;
- each of Tokai’s current directors;
- Tokai’s principal executive officer, and its two other executive officers who served during the year ended December 31, 2016, whom, collectively, Tokai refers to as its named executive officers; and
- all executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Unless otherwise indicated below, to Tokai’s knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable. Shares of Tokai common stock subject to options that are currently exercisable or exercisable within 60 days of December 31, 2016 are deemed to be outstanding and to be beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Percentage ownership of Tokai common stock in the table is based on 22,641,651 shares of Tokai common stock issued and outstanding on December 31, 2016. Unless otherwise indicated, the address of each of the individuals and entities named below is c/o Tokai Pharmaceuticals, Inc., 255 State Street, 6th Floor, Boston, Massachusetts 02109. Beneficial ownership representing less than one percent of Tokai’s outstanding common stock is denoted with an “*.”

Name of Beneficial Owner	Number of Shares Beneficially Owned	%
5% Stockholders:		
Entities affiliated with Apple Tree Partners (1)	7,912,079	34.9
Novartis BioVentures Ltd. (2)	4,493,458	19.8
Trusts and other entities affiliated with Muneer A. Satter (3)	1,775,188	7.8
Executive Officers and Directors:		
Jodie P. Morrison (4)	765,809	3.3
John S. McBride (5)	203,818	*
Seth L. Harrison, M.D. (6)	8,136,773	35.9
Stephen Buckley, Jr. (7)	39,666	*
Cheryl L. Cohen (8)	14,583	*
David A. Kessler, M.D. (9)	40,855	*
Joseph A. Yanchik, III (10)	59,204	*
All directors and executive officers as a group (7 persons) (11)	9,260,708	39.1

1) Based on information provided in a Schedule 13D filed by Apple Tree Partners II, L.P. on September 30, 2014. Consists of (i) 4,218,641 shares of common stock held by Apple Tree Partners II, L.P., (ii) 3,568,438 shares of common stock held by Apple Tree Partners II—Annex, L.P. and (iii) 125,000 shares of common stock held by Apple Tree Partners IV, L.P. Dr. Seth L. Harrison, a member of Tokai’s board of directors, is a principal of the general partner of each of Apple Tree Partners II, L.P., Apple Tree Partners II—Annex, L.P. and Apple Tree Partners IV, L.P., and Dr. Harrison disclaims beneficial ownership of the shares held by each of Apple Tree Partners II, L.P., Apple Tree Partners II—Annex, L.P. and Apple Tree

Table of Contents

Partners IV, L.P., except to the extent of his pecuniary interest therein. Dr. Harrison has sole voting and investment control and power over the shares held by Apple Tree Partners II, L.P., Apple Tree Partners II—Annex, L.P. and Apple Tree Partners IV, L.P. The address of Apple Tree Partners is 230 Park Avenue, Suite 2800, New York, NY 10169.

- 2) Based on information provided in a Schedule 13D and Form 4 filed by Novartis BioVentures Ltd., a Bermuda corporation, on October 1, 2014 and July 17, 2015, respectively. Novartis BioVentures Ltd. is a wholly-owned indirect subsidiary of Novartis AG, which is an indirect beneficial owner of the reported securities. The address of Novartis BioVentures Ltd. is PO Box HM 2899, Hamilton HM LX, Bermuda.
- 3) Based on information provided in a Schedule 13G filed by Muneer A. Satter on February 12, 2016. Consists of (i) 745,969 shares of common stock that are held by the Muneer A. Satter Revocable Trust for which Mr. Satter serves as trustee and, in such capacity, has sole voting and dispositive power over all such shares and (ii) 1,029,219 shares of common stock that are held by various other trusts and other entities for which Mr. Satter serves as trustee, investment advisor or manager and, in such capacity, has sole voting and dispositive power over all such shares. The address for Mr. Satter is Muneer A. Satter, c/o Satter Investment Management, LLC, 676 North Michigan Avenue, Suite 4000, Chicago, IL 60611.
- 4) Consists of (i) 57,566 shares of common stock and (ii) 708,243 shares of common stock underlying options that are exercisable as of December 31, 2016 or will become exercisable within 60 days after such date.
- 5) Consists of shares of common stock underlying options that are exercisable as of December 31, 2016 or will become exercisable within 60 days after such date.
- 6) Consists of (i) 212,694 shares of common stock held by Dr. Harrison, (ii) 12,000 shares of common stock underlying options that are exercisable as of December 31, 2016 or will become exercisable within 60 days after such date, (iii) 4,218,641 shares of common stock held by Apple Tree Partners II, L.P., (iv) 3,568,438 shares of common stock held by Apple Tree Partners II—Annex, L.P. and (v) 125,000 shares of common stock held by Apple Tree Partners IV, L.P. Dr. Seth L. Harrison, a member of Tokai's board of directors, is a principal of the general partner of each of Apple Tree Partners II, L.P., Apple Tree Partners II—Annex, L.P. and Apple Tree Partners IV, L.P., and Dr. Harrison disclaims beneficial ownership of the shares held by each of Apple Tree Partners II, L.P., Apple Tree Partners II—Annex, L.P. and Apple Tree Partners IV, L.P., except to the extent of his pecuniary interest therein. Dr. Harrison has sole voting and investment control and power over the shares held by Apple Tree Partners II, L.P., Apple Tree Partners II—Annex, L.P. and Apple Tree Partners IV, L.P.
- 7) Consists of (i) 11,000 shares of common stock and (ii) 28,666 shares of common stock underlying options that are exercisable as of December 31, 2016 or will become exercisable within 60 days after such date.
- 8) Consists of shares of common stock underlying options that are exercisable as of December 31, 2016 or will become exercisable within 60 days after such date.
- 9) Consists of shares of common stock underlying options that are exercisable as of December 31, 2016 or will become exercisable within 60 days after such date.
- 10) Consists of (i) 25,546 shares of common stock and (ii) 33,658 shares of common stock underlying options that are exercisable as of December 31, 2016 or will become exercisable within 60 days after such date.
- 11) Consists of (i) 8,218,885 shares of common stock and (ii) 1,041,823 shares of common stock underlying options that are exercisable as of December 31, 2016 or will become exercisable within 60 days after such date.

UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION

The following information does not give effect to the proposed reverse stock split described in the section entitled "Reverse Stock Split Proposal," beginning on page 118 of this proxy statement.

In the unaudited pro forma combined financial information, the Otic Transaction has been accounted for as a business combination using the acquisition method of accounting under the provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 805, *Business Combinations* ("ASC 805"). The Otic Transaction will be accounted for as a reverse acquisition with Otic being deemed the acquiring company for accounting purposes. Under ASC 805, Otic, as the accounting acquirer, will record the assets acquired and liabilities assumed of Tokai in the Otic Transaction at their fair values as of the acquisition date. The unaudited pro forma combined financial information also gives effect to the related Equity Financing as described on page 115 of this proxy statement.

Otic was determined to be the accounting acquirer based on an analysis of the criteria outlined in ASC 805 and the facts and circumstances specific to the Otic Transaction, including: (1) shareholders of Otic are expected to own approximately 60% of the voting interests of the combined company immediately following the closing of the transaction; (2) the majority of the board of directors of the combined company will be composed of directors designated by Otic under the terms of the Share Purchase Agreement; and (3) existing members of Otic management will be the management of the combined company.

Because Otic has been determined to be the accounting acquirer in the Otic Transaction, but not the legal acquirer, the Otic Transaction is deemed a reverse acquisition under the guidance of ASC 805. As a result, upon consummation of the Otic Transaction, the historical financial statements of Otic will become the historical financial statements of the combined company.

The unaudited pro forma combined balance sheet as of September 30, 2016 gives effect to the Otic Transaction and Equity Financing as if each of them took place on September 30, 2016. The unaudited pro forma combined statements of operations for the nine months ended September 30, 2016 and for the year ended December 31, 2015 give effect to the Otic Transaction and Equity Financing as if each of them took place as of January 1, 2015. The historical financial statements of Tokai and Otic have been adjusted to give pro forma effect to events that are (1) directly attributable to the Otic Transaction and Equity Financing, (2) factually supportable, and (3) with respect to the unaudited pro forma combined statements of operations, expected to have a continuing impact on the combined results of operations of the combined company.

The unaudited pro forma combined financial information is based on assumptions and adjustments that are described in the accompanying notes. The application of the acquisition method of accounting is dependent upon certain valuations and other studies that have yet to be completed. Accordingly, the pro forma adjustments reflected in the unaudited pro forma combined financial information are preliminary and based on estimates, subject to further revision as additional information becomes available and additional analyses are performed, and have been made solely for the purpose of providing the unaudited pro forma combined financial information. Differences between the preliminary adjustments reflected in the unaudited pro forma combined financial information and the final application of the acquisition method of accounting, which is expected to be completed as soon as practicable after the closing of the Otic Transaction, may arise and those differences could have a material impact on the accompanying unaudited pro forma combined financial information and the combined company's future results of operations and financial position. In addition, differences between the preliminary and final adjustments will likely occur as a result of the amount of cash used for Tokai's operations, changes in fair value of the Tokai common stock and other changes in Tokai's assets and liabilities between September 30, 2016 and the closing date of the Otic Transaction.

[Table of Contents](#)

The unaudited pro forma combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma combined financial information has been prepared for illustrative purposes only and is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Tokai and Otic been a combined company during the specified periods.

The unaudited pro forma combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of Tokai and Otic and the sections of this proxy statement entitled “*Tokai’s Management’s Discussion and Analysis of Financial Condition and Results of Operations*” and “*Otic’s Management’s Discussion and Analysis of Financial Condition and Results of Operations*.” Tokai’s historical unaudited financial statements for the nine months ended September 30, 2016 and 2015 and its historical audited consolidated financial statements for the years ended December 31, 2015, 2014 and 2013 are included elsewhere in this proxy statement. Otic’s historical unaudited consolidated financial statements for the nine months ended September 30, 2016 and 2015 and its historical audited consolidated financial statements for the years ended December 31, 2015 and 2014 are also included elsewhere in this proxy statement.

[Table of Contents](#)

Unaudited Pro Forma Combined Balance Sheet
September 30, 2016
(in thousands)

	<u>Historical Otic</u>	<u>Historical Tokai</u>	<u>Pro Forma Adjustments</u>		<u>Pro Forma Combined</u>
Assets					
Current assets:					
Cash and cash equivalents	\$ 2,372	\$ 18,630	\$ 4,000	A	\$ 28,121
			3,119	B	
Restricted cash	14	—	—		14
Marketable securities	—	16,088	—		16,088
Prepaid expenses and other current assets	71	1,616	—		1,687
Total current assets	2,457	36,334	7,119		45,910
Property and equipment, net	72	117	—		189
Restricted cash	—	270	—		270
Total assets	<u>\$ 2,529</u>	<u>\$ 36,721</u>	<u>\$ 7,119</u>		<u>\$ 46,369</u>
Liabilities and Stockholders' Equity (Deficit)					
Current liabilities:					
Accounts payable	\$ 68	\$ 886	\$ —		\$ 954
Accrued expenses	230	5,458	6,100	C	11,714
			(74)	D	
Convertible debt	3,447	—	(3,447)	E	—
Total current liabilities	3,745	6,344	2,579		12,668
Long-term liabilities	—	120	(120)	D	—
Total liabilities	<u>3,745</u>	<u>6,464</u>	<u>2,459</u>		<u>12,668</u>
Stockholders' equity (deficit):					
Preferred stock	11	—	(11)	E	—
Common stock	1	23	(23)	F	59
			4	A	
			23	G	
			31	H	
Additional paid-in capital	11,356	195,891	(195,891)	F	46,166
			3,996	A	
			3,119	B	
			3,749	E	
			23,977	G	
			(31)	H	
Receipts on account of Preferred A shares	291	—	(291)	E	—
Accumulated deficit	(12,875)	(165,660)	165,660	F	(12,524)
			(6,100)	C	
			6,451	I	
Accumulated other comprehensive income (loss)	—	3	(3)	F	—
Total stockholders' equity (deficit)	<u>(1,216)</u>	<u>30,257</u>	<u>4,660</u>		<u>33,701</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 2,529</u>	<u>\$ 36,721</u>	<u>\$ 7,119</u>		<u>\$ 46,369</u>

The accompanying notes are an integral part of these unaudited pro forma combined financial statements.

[Table of Contents](#)

Unaudited Pro Forma Combined Statement of Operations
Nine Months Ended September 30, 2016
(in thousands, except share and per share data)

	Historical Otic	Historical Tokai	Pro Forma Adjustments		Pro Forma Combined
Revenue	\$ —	\$ —	\$ —		\$ —
Operating expenses:					
Research and development	2,335	23,988	—		26,323
General and administrative	1,326	10,375	(50)	J	11,651
Total operating expenses	<u>3,661</u>	<u>34,363</u>	<u>(50)</u>		<u>37,974</u>
Loss from operations	(3,661)	(34,363)	50		(37,974)
Other income (expense), net	(479)	141	517	K	179
Net loss (1)	<u>\$ (4,140)</u>	<u>\$ (34,222)</u>	<u>\$ 567</u>		<u>\$ (37,795)</u>
Net loss per share, basic and diluted	<u>\$ (1.01)</u>	<u>\$ (1.51)</u>			<u>\$ (0.67)</u>
Weighted average common shares outstanding, basic and diluted	<u>711,231</u>	<u>22,632,287</u>	<u>33,131,823</u>	L	<u>56,475,341</u>

(1) Otic's historical net loss attributable to ordinary shareholders was \$(718) for the nine months ended September 30, 2016.

The accompanying notes are an integral part of these unaudited pro forma combined financial statements.

[Table of Contents](#)

Unaudited Pro Forma Combined Statement of Operations
Year Ended December 31, 2015
(in thousands, except share and per share data)

	Historical Otic	Historical Tokai	Pro Forma Adjustments	Pro Forma Combined
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	2,774	32,638	—	35,412
General and administrative	1,415	12,623	—	14,038
Total operating expenses	4,189	45,261	—	49,450
Loss from operations	(4,189)	(45,261)	—	(49,450)
Other income (expense), net	(25)	174	—	149
Net loss (1)	<u>\$ (4,214)</u>	<u>\$ (45,087)</u>	<u>\$ —</u>	<u>\$ (49,301)</u>
Net loss per share, basic and diluted	<u>\$ (1.13)</u>	<u>\$ (2.01)</u>		<u>\$ (0.93)</u>
Weighted average common shares outstanding, basic and diluted	<u>605,520</u>	<u>22,484,343</u>	<u>29,677,990</u>	M <u>52,767,853</u>

(1) Otic's historical net loss attributable to ordinary shareholders was \$(687) for the year ended December 31, 2015.

The accompanying notes are an integral part of these unaudited pro forma combined financial statements.

Notes to the Unaudited Pro Forma Combined Financial Information

1. Description of the Transactions and Basis of Presentation

Description of the Otic Transaction

Upon the terms and subject to the conditions set forth in the Share Purchase Agreement, dated as of December 21, 2016, by and among Tokai, Otic, and the shareholders of Otic, Tokai will acquire all of the ordinary and preferred shares of Otic in exchange for the issuance to the Sellers of a specified number of shares of Tokai common stock and will assume all outstanding share options and warrants of Otic. Following the Otic Transaction, Otic will be a wholly owned subsidiary of Tokai.

Based on the outstanding share capital of Otic as of the date of the Share Purchase Agreement and the shares issuable upon exercise of warrants to purchase shares of Otic and the conversion of certain outstanding debt facilities of Otic into shares of Otic that are expected to be exercised or converted prior to the closing of the Otic Transaction, Tokai expects to issue shares of Tokai common stock in the Otic Transaction. If all of Otic's outstanding options and warrants are exercised prior to closing, Tokai will issue a total of 36,911,631 shares of Tokai common stock in the Otic Transaction. Following the closing of the Otic Transaction, the stockholders of Otic are expected to hold approximately 60% of the outstanding shares of Tokai common stock, excluding for this purpose the effect on ownership of the issuance of shares in the Equity Financing. The relative percentage ownership of the combined company was derived using a stipulated value of Otic of approximately \$50.0 million and of Tokai of approximately \$33.0 million.

The Otic Transaction is expected to close in the first half of 2017, subject to customary closing conditions, including the approval of the Otic Transaction by Tokai's stockholders.

Description of the Equity Financing

In connection with the Otic Transaction, Tokai has entered into the Tokai Stock Purchase Agreement dated January , 2017 with Otic and certain purchasers set forth therein pursuant to which the purchasers have agreed to purchase shares of Tokai common stock at a price of \$ per share. The Tokai Stock Purchase Agreement provides that the purchase and sale of the Tokai common stock will occur immediately following the closing of the Otic Transaction.

Basis of Presentation

The unaudited pro forma combined financial information was prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and pursuant to the rules and regulations of Article 11 of SEC Regulation S-X. The unaudited pro forma combined balance sheet as of September 30, 2016 was prepared using the historical balance sheets of Tokai and Otic as of September 30, 2016 and gives effect to the Otic Transaction and Equity Financing as if each occurred on September 30, 2016. The unaudited pro forma combined statements of operations for the year ended December 31, 2015 and the nine months ended September 30, 2016 were prepared using the historical statements of operations of Tokai and Otic for the year ended December 31, 2015 and the nine months ended September 30, 2016 and give effect to the Otic Transaction and Equity Financing as if each occurred on January 1, 2015.

Otic has preliminarily concluded that the Otic Transaction represents a business combination pursuant to ASC 805. In addition, because Otic has been determined to be the accounting acquirer in the Otic Transaction, but not the legal acquirer, the Otic Transaction is deemed a reverse acquisition under the guidance of ASC 805. Otic has not yet completed a valuation analysis of the fair market value of Tokai's assets to be acquired and liabilities to be assumed. Using the estimated total consideration for the Otic Transaction, Otic has preliminarily allocated such consideration to the assets acquired and liabilities assumed of Tokai in the Otic Transaction based on the amounts reported in Tokai's balance sheet as of September 30, 2016, as Otic management believes that

[Table of Contents](#)

such amounts approximate the fair values, as of that date, of the assets to be acquired and the liabilities to be assumed by Otic in the Otic Transaction. This preliminary purchase price allocation was used to prepare pro forma adjustments in the unaudited pro forma combined balance sheet. The final purchase price allocation will be determined when Otic has determined the final consideration paid in the Otic Transaction and completed the detailed valuations and other studies and necessary calculations. The final purchase price allocation could differ materially from the preliminary purchase price allocation used to prepare the pro forma adjustments and the unaudited pro forma combined balance sheet. The final purchase price allocation may (1) result in allocations to intangible assets and goodwill based on the results of certain valuations and other studies that have yet to be completed, (2) include other changes to assets and liabilities and (3) include changes to the fair value of purchase consideration in the Otic Transaction.

Tokai and Otic did not record any income tax benefits for the net losses incurred and tax credits earned during the nine months ended September 30, 2016 and the year ended December 31, 2015 due to the uncertainty of realizing a benefit from those items. Each company maintains a full valuation allowance on its net deferred tax assets. Accordingly, no tax-related adjustments have been reflected for the pro forma adjustments described in Note 4.

2. Preliminary Purchase Price

Pursuant to the Share Purchase Agreement, at the closing of the Otic Transaction, Tokai expects to issue to Otic stockholders a number of shares of Tokai common stock representing approximately 60% of the outstanding shares of common stock of the combined company. The estimated preliminary purchase price, which represents the consideration transferred to Tokai stockholders in the Otic Transaction, is calculated based on the fair value of the common stock of the combined company that Tokai stockholders will own as of the closing date of the transaction because, with no active trading market for shares of Otic, the fair value of the Tokai common stock represents a more reliable measure of the fair value of consideration transferred in the Otic Transaction. Accordingly, the accompanying unaudited pro forma combined financial information reflects an estimated purchase price of approximately \$24.0 million, which consists of the following:

Estimated number of shares of the combined company to be owned by Tokai stockholders (a)	22,641,651
Multiplied by the fair value per share of Tokai common stock (b)	\$ 1.06
Estimated purchase price	<u>\$ 24,000,150</u>

- (a) The final purchase price will be determined based on the number of shares of common stock of the combined company that Tokai stockholders own as of the closing date of the Otic Transaction. For purposes of this unaudited pro forma combined financial information, the estimated number of shares represents the 22,641,651 shares of Tokai common stock outstanding as of September 30, 2016, which does not include the impact of a proposed reverse stock split that is expected to be effected prior to consummation of the Otic Transaction.
- (b) The estimated purchase price was based on the last reported sale price of Tokai common stock on The NASDAQ Global Market on January 5, 2017. The requirement to base the final purchase price on the number of shares of and fair market value of Tokai common stock outstanding immediately prior to the closing of the Otic Transaction could result in a purchase price and bargain purchase gain different from that assumed in this unaudited pro forma combined financial information, and that difference may be material. A 10% increase (decrease) to the Tokai share price from the \$1.06 per share price assumed in the unaudited pro forma combined financial information would increase (decrease) the purchase price by \$2.4 million, with a corresponding change to the bargain purchase gain. Therefore, the estimated consideration expected to be transferred reflected in this unaudited pro forma combined financial information does not purport to represent what the actual consideration transferred will be when the Otic Transaction is completed. The actual purchase price will fluctuate until the closing date of the Otic

[Table of Contents](#)

Transaction, and the final valuation of the purchase consideration could differ significantly from the current estimate.

The following table illustrates the effect of a change in Tokai's common stock price on the estimated total purchase price and estimated bargain purchase gain in the Otic Transaction (in thousands, except per share amounts):

Change in Stock Price	Tokai Stock Price	Estimated Purchase Price	Estimated Bargain Purchase Gain
Increase of 10%	\$ 1.17	\$ 26,400	\$ 4,051
Decrease of 10%	\$ 0.95	\$ 21,600	\$ 8,851
Increase of 20%	\$ 1.27	\$ 28,800	\$ 1,651
Decrease of 20%	\$ 0.85	\$ 19,200	\$ 11,251

Under the acquisition method of accounting, the total purchase price is allocated to the acquired tangible and intangible assets and assumed liabilities of Tokai based on their estimated fair values as of the Otic Transaction closing date. Because the estimated consideration to be paid by Otic in the Otic Transaction is less than the estimated fair values of Tokai's net assets acquired, a bargain purchase gain equal to the difference has been reflected in the unaudited pro forma combined balance sheet. The bargain purchase gain of \$6.5 million determined for the purpose of this unaudited pro forma combined financial information has been calculated using the carrying values of the net assets of Tokai as of September 30, 2016. The final determination of whether a bargain purchase gain exists and the amount of such gain, if any, will be based on (1) the final determination of the fair values of the net assets of Tokai acquired on the closing date of the Otic Transaction and (2) the fair value of purchase consideration on the closing date of the Otic Transaction, both of which may be materially different from the amounts as of September 30, 2016. Management believes that the net assets of Tokai will decline prior to the Otic Transaction close, which would reduce or eliminate the bargain purchase gain. The bargain purchase gain has not been reflected in the pro forma combined statements of operations as it will not have a continuing impact on the operating results of the combined company.

The preliminary allocation of the preliminary estimated purchase price to the acquired assets and liabilities assumed of Tokai, based on their estimated fair values as of September 30, 2016, is as follows (in thousands):

Cash, cash equivalents and marketable securities	\$ 34,718
Other assets	1,886
Property and equipment	117
Accounts payable, accrued expenses and other liabilities	(6,270)
Net assets acquired	30,451
Less: estimated purchase price	(24,000)
Bargain purchase gain	\$ 6,451

The application of the acquisition method of accounting is dependent upon certain valuations and other studies that have yet to be completed. The purchase price allocation will remain preliminary until Otic management determines the fair values of assets acquired and liabilities assumed. The final determination of the purchase price allocation is anticipated to be completed as soon as practicable after completion of the Otic Transaction and will be based on the fair values of the assets acquired and liabilities assumed as of the Otic Transaction closing date. The final amounts allocated to assets acquired and liabilities assumed could differ significantly from the amounts presented in the unaudited pro forma combined financial statements for the reasons described in Note 1.

[Table of Contents](#)

3. Shares of Tokai Common Stock Issued to Otic Shareholders upon Closing of the Otic Transaction

Prior to the closing of the Otic Transaction (1) all outstanding preferred shares of Otic will be converted into ordinary shares of Otic, (2) outstanding warrants to purchase Preferred B shares and Preferred C shares of Otic will be exercised and subsequently converted into ordinary shares of Otic and (3) all amounts outstanding under Otic's convertible loan agreement will be converted into Preferred C shares of Otic and subsequently converted into ordinary shares of Otic. Based on the 740,215 ordinary shares of Otic outstanding as of September 30, 2016 and the issuance of shares pursuant to (1) through (3) above, the number of Otic ordinary shares outstanding immediately prior to the closing of the Otic Transaction was estimated for the purpose of the unaudited pro forma combined financial information to be 7,561,036. Based on that estimate and the exchange ratio provided in the Share Purchase Agreement of 4.255, Tokai expects to issue 32,172,208 shares of Tokai common stock in the Otic Transaction, determined as follows:

Ordinary shares of Otic outstanding as of September 30, 2016	740,215
Preferred shares of Otic outstanding as of September 30, 2016 (as converted to ordinary shares)	4,271,068
Shares issuable upon exercise warrants to purchase Preferred B and Preferred C shares of Otic (as converted to ordinary shares)	1,942,908
Shares issuable upon conversion of convertible debt into Preferred C shares of Otic (as converted to ordinary shares)	606,845
Ordinary shares of Otic assumed outstanding prior to the closing of the Otic Transaction	7,561,036
Exchange ratio	4.255
Estimated shares of Tokai common stock issued to Otic shareholders upon closing of the Otic Transaction	<u>32,172,208</u>

The actual number of shares of Tokai common stock that Otic shareholders will receive at closing depends on an allocation schedule that Otic will deliver to Tokai prior to closing.

4. Pro Forma Adjustments

The unaudited pro forma combined financial information includes pro forma adjustments that are (1) directly attributable to the Otic Transaction and Equity Financing, (2) factually supportable, and (3) with respect to the unaudited pro forma combined statements of operations, expected to have a continuing impact on the results of operations of the combined company.

Based on Otic's management's review of Tokai's summary of significant accounting policies, the nature and amount of any adjustments to the historical financial statements of Tokai to conform to the accounting policies of Otic are not expected to be significant. Tokai does not anticipate declaring and paying any cash dividends prior to the closing of the Otic Transaction and anticipates that its net cash at the closing will be approximately \$25.0 million.

The unaudited pro forma combined financial information does not reflect the proposed Tokai reverse stock split that is expected to be effected prior to consummation of the Otic Transaction.

The pro forma adjustments, based on preliminary estimates that may change significantly as additional information is obtained, are as follows:

- A. To reflect proceeds of \$4.0 million from the purchase of an assumed 3,603,604 shares of Tokai common stock at an assumed price of \$1.11 per share pursuant to the Equity Financing entered into in connection with the Otic Transaction.

Table of Contents

- B. To reflect proceeds of \$3.1 million from the exercise of outstanding Otic warrants prior to the closing of the Otic Transaction.
- C. To reflect accrued liabilities of \$6.1 million that are directly attributable to the closing of the Otic Transaction, including approximately \$2.3 million in employee severance and change-in-control obligations for Tokai employees that will be reflected in the Otic statements of operations following the closing of the Otic Transaction and estimated transaction costs to complete the Otic Transaction of approximately \$2.1 million and \$1.7 million for Tokai and Otic, respectively, principally consisting of banker fees, legal expenses, and auditor and printer fees to be incurred by Otic and Tokai. These pro forma adjustments are not reflected in the unaudited pro forma combined statements of operations as these amounts are not expected to have a continuing impact on the operating results of the combined company.
- D. To reflect the removal of Tokai deferred rent as a result of the acquisition method of accounting.
- E. To reflect the conversion of (1) all outstanding Otic preferred shares into ordinary shares of Otic, (2) all amounts outstanding under Otic's convertible loan agreement into Preferred C shares of Otic that will subsequently be converted into ordinary shares of Otic and (3) receipts on account of Preferred A shares into ordinary shares of Otic, each occurring prior to the closing of the Otic Transaction (see Note 3).
- F. To reflect the elimination of Tokai's historical stockholders' equity.
- G. To reflect the estimated purchase consideration transferred to Tokai stockholders.
- H. To reflect an increase in the par value of common stock based on the par value of Tokai common stock to be issued to Otic shareholders in connection with the Otic Transaction after applying the exchange ratio of 4.255, as follows (dollar amounts in thousands, except per share amounts):

Ordinary shares of Otic assumed outstanding prior to the closing of the Otic Transaction (see Note 3)	7,561,036
Exchange ratio	4.255
Estimated shares of Tokai common stock issued to Otic shareholders upon closing of the Otic Transaction	32,172,208
Multiplied by the par value per share of Tokai common stock	\$ 0.001
Par value of Tokai common stock issued to Otic shareholders	\$ 32
Less historical par value of Otic ordinary shares	(1)
Net pro forma adjustment to common stock	\$ 31

- I. To reflect the estimated bargain purchase gain recognized as a result of the Otic Transaction.
- J. To reflect the elimination of transaction costs incurred by Tokai during the nine months ended September 30, 2016. No transaction costs were incurred by Otic during the nine months ended September 30, 2016. These amounts have been eliminated on a pro forma basis as they are not expected to have a continuing effect on the operating results of the combined company.
- K. To reflect the elimination of other expense of \$0.5 million recorded in Otic's historical statement of operations for the nine months ended September 30, 2016 related to a fair value adjustment for amounts outstanding under Otic's convertible loan agreement because the unaudited pro forma combined statement of operations for the same period assumes that the conversion of all amounts outstanding under the loan agreement had occurred on the issuance date of the related note, July 11, 2016.
- L. To reflect an increase in the weighted average shares outstanding for the period after giving effect to the issuance of Tokai common stock in connection with the Otic Transaction and Equity Financing. The adjustment has been prepared to give effect to shares issued from (i) the conversion of Otic preferred shares, (ii) the exercise of Otic warrants, (iii) the conversion of all amounts outstanding under Otic's convertible loan agreement and (iv) the Equity Financing, as if such

[Table of Contents](#)

issuances had occurred on the later of January 1, 2015 or the issuance date of the underlying securities. The following table presents these pro forma adjustments without giving effect to the proposed reverse stock split, as follows (presented on a weighted average basis):

Otic weighted average ordinary shares outstanding for the period	711,231
Otic ordinary shares issued upon conversion of preferred shares prior to close of the Otic Transaction	4,271,068
Otic warrants exercised prior to close of the Otic Transaction (as converted to ordinary shares)	1,942,908
Otic shares issued upon conversion of convertible loan (as converted to ordinary shares)	<u>179,396</u>
Otic weighted average ordinary shares outstanding for the period	7,104,603
Exchange ratio	<u>4.255</u>
Pro forma Otic weighted average shares outstanding for the period	30,230,086
Tokai common shares outstanding upon closing of the Otic Transaction	22,641,651
Tokai common shares issued pursuant to the Equity Financing	<u>3,603,604</u>
Pro forma combined weighted average common shares outstanding for the period	<u><u>56,475,341</u></u>

- M. To reflect an increase in the weighted average shares outstanding for the period after giving effect to the issuance of Tokai common stock in connection with the Otic Transaction and Equity Financing. The adjustment has been prepared to give effect to shares issued from (i) the conversion of Otic preferred shares, (ii) the exercise of Otic warrants and (iii) the Equity Financing, as if the such issuances had occurred on the later of January 1, 2015 or the issuance date of the underlying securities. The following table presents these pro forma adjustments without giving effect to the proposed reverse stock split, as follows (presented on a weighted average basis):

Otic weighted average ordinary shares outstanding for the period	605,520
Otic ordinary shares issued upon conversion of preferred shares prior to close of the Otic Transaction	3,684,850
Otic warrants exercised prior to close of the Otic Transaction (as converted to ordinary shares)	<u>1,942,908</u>
Otic weighted average ordinary shares outstanding for the period	6,233,278
Exchange ratio	<u>4.255</u>
Pro forma Otic weighted average shares outstanding for the period	26,522,598
Tokai common shares outstanding upon closing of the Otic Transaction	22,641,651
Tokai common shares issued pursuant to the Equity Financing	<u>3,603,604</u>
Pro forma combined weighted average common shares outstanding for the period	<u><u>52,767,853</u></u>

WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION BY REFERENCE

Tokai files annual, quarterly and current reports, proxy statements and other information with the SEC. Tokai's SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. Copies of certain information filed by Tokai with the SEC are also available on Tokai's website at <http://www.tokai-pharma.com>. You may also read and copy any document Tokai files at the SEC's Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

Statements contained in this proxy statement, or in any document incorporated by reference in this proxy statement, regarding the contents of any contract or other document are not necessarily complete and each such statement is qualified in its entirety by reference to that contract or other document filed as an exhibit with the SEC. The SEC allows us to incorporate by reference into this proxy statement documents Tokai files with the SEC. This means that Tokai can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be a part of this proxy statement, and later information that Tokai files with the SEC will update and supersede that information. proxy statement incorporates by reference the documents listed below and any documents filed by us pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (in each case, other than those documents or the portions of those documents not deemed to be filed) after the date of this proxy statement and before the date of the special meeting.

- Annual Report on Form 10-K for the fiscal year ended December 31, 2015, including the information specifically incorporated by reference into the Annual Report on Form 10-K from Tokai's definitive proxy statement for the 2016 annual meeting of stockholders;
- Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2016, June 30, 2016 and September 30, 2016;
- Current Reports on Form 8-K filed January 7, 2016 (solely with respect to item 8.01 therein), May 31, 2016, June 16, 2016, July 26, 2016 (solely with respect to item 8.01 therein), August 3, 2016, October 12, 2016, and December 22, 2016; and
- The description of Tokai's common stock contained in its Registration Statement on Form 8-A filed on September 12, 2014, including any amendments or reports filed for the purpose of updating such description.

Tokai has supplied all information contained in this proxy statement relating to Tokai, and Otic has supplied all information contained in this proxy statement relating to Otic.

Any person, including any beneficial owner of shares of Tokai common stock, to whom this proxy statement delivered may request copies of the proxy statement and any of the documents incorporated by reference in this document or other information concerning us by written or telephonic request directed to Tokai Pharmaceuticals, Inc., 255 State Street, 6th floor, Boston, Massachusetts 02109, Attn: Investor Relations, or from the SEC through the SEC website at the address provided above. Documents incorporated by reference are available without charge, excluding any exhibits to those documents unless the exhibit is specifically incorporated by reference into those documents.

If you would like to request documents from Otic, please send a request in writing or by telephone to Otic at 19900 MacArthur Blvd., Suite 550, Irvine, CA 92612 or (949) 238-8090.

THIS PROXY STATEMENT DOES NOT CONSTITUTE THE SOLICITATION OF A PROXY IN ANY JURISDICTION TO OR FROM ANY PERSON TO WHOM OR FROM WHOM IT IS UNLAWFUL TO MAKE SUCH PROXY SOLICITATION IN THAT JURISDICTION. YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED IN THIS PROXY STATEMENT TO VOTE YOUR SHARES AT THE SPECIAL MEETING. TOKAI HAS NOT AUTHORIZED ANYONE TO

[Table of Contents](#)

PROVIDE YOU WITH INFORMATION THAT IS DIFFERENT FROM WHAT IS CONTAINED IN THIS PROXY STATEMENT. THIS PROXY STATEMENT IS DATED . YOU SHOULD NOT ASSUME THAT THE INFORMATION CONTAINED IN THIS PROXY STATEMENT IS ACCURATE AS OF ANY DATE OTHER THAN THAT DATE, AND THE MAILING OF THIS PROXY STATEMENT TO STOCKHOLDERS DOES NOT CREATE ANY IMPLICATION TO THE CONTRARY.

OTHER MATTERS

Stockholder Proposals

As of the date of this proxy statement, the Tokai board of directors does not intend to present any matters other than those described herein at the special meeting and is unaware of any matters to be presented by other parties. If other matters are properly brought before the special meeting for action by the stockholders, proxies will be voted in accordance with the recommendation of the Tokai board of directors or, in the absence of such a recommendation, in the discretion of the proxy holder.

Any stockholder nominations or proposals for business intended to be presented at Tokai's next annual meeting must be submitted to Tokai as set forth below.

Stockholder Proposals Included in Proxy Statement

In order to be considered for inclusion in Tokai's proxy statement and proxy card relating to Tokai's 2017 annual meeting of stockholders, stockholder proposals must have been received by Tokai no later than December 30, 2016, which is 120 days prior to the first anniversary of the mailing date of Tokai's proxy statement relating to its 2016 annual meeting, unless the date of the 2017 annual meeting of stockholders is changed by more than 30 days from the anniversary of Tokai's 2016 annual meeting, in which case, the deadline for such proposals will be a reasonable time before Tokai begins to print and send its proxy materials. Upon receipt of any such proposal, Tokai will determine whether or not to include such proposal in the proxy statement and proxy card in accordance with regulations governing the solicitation of proxies.

Stockholder Proposals Not Included in Proxy Statement

In addition, Tokai's by-laws establish an advance notice procedure for nominations for election to its board of directors and other matters that stockholders wish to present for action at an annual meeting other than those to be included in its proxy statement. In general, Tokai must receive other proposals of stockholders (including director nominations) intended to be presented at the 2017 annual meeting of stockholders but not included in the proxy statement by March 17, 2017, but not before February 15, 2017, which is not less than 90 days nor more than 120 days prior to the anniversary date of the immediately preceding annual meeting. However, if the date of the annual meeting is more than 20 days before or more than 60 days after such anniversary date, notice must be received no earlier than the close of business 120 calendar days prior to such annual meeting and no later than the close of business on the later of 90 days prior to such annual meeting and 10 days following the day on which notice of the date of such annual meeting was mailed or public announcement of the date of such annual meeting was first made. If the stockholder fails to give notice by these dates, then the persons named as proxies in the proxies solicited by the board of directors for the 2017 annual meeting of stockholders may exercise discretionary voting power regarding any such proposal. Stockholders are advised to review Tokai's by-laws which also specify requirements as to the form and content of a stockholder's notice.

Any proposals, notices or information about proposed director candidates should be sent to Tokai Pharmaceuticals, Inc., Attention: Nominating and Corporate Governance Committee, 255 State Street, 6th Floor, Boston, Massachusetts 02109.

Communication with the Tokai Board of Directors

Should stockholders wish to communicate with the Tokai board of directors or any specified individual directors, such correspondence should be sent to Tokai Pharmaceuticals, Inc., Attention: Board of Directors, 255 State Street, 6th Floor, Boston, Massachusetts 02109.

[Table of Contents](#)

INDEX TO TOKAI CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
<i>Audited Consolidated Financial Statements for the Years Ended December 31, 2015, 2014 and 2013</i>	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations and Comprehensive Loss	F-4
Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7
 <i>Unaudited Interim Financial Statements for the Three and Nine Months Ended September 30, 2016 and 2015</i>	
Balance Sheets as of September 30, 2016 and December 31, 2015	F-26
Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015	F-27
Statements of Cash Flows for the nine months ended September 30, 2016 and 2015	F-28
Notes to Financial Statements	F-29

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Tokai Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of changes in redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Tokai Pharmaceuticals, Inc. and its subsidiary at December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 10, 2016

[Table of Contents](#)

Tokai Pharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	<u>December 31,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,023	\$ 105,256
Marketable securities	39,934	—
Prepaid expenses and other current assets	3,213	2,255
Total current assets	67,170	107,511
Property and equipment, net	489	33
Restricted cash	270	200
Other assets	45	—
Total assets	<u>\$ 67,974</u>	<u>\$ 107,744</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,208	\$ 765
Accrued expenses	4,954	3,478
Total current liabilities	6,162	4,243
Other long term liabilities	88	—
Total liabilities	<u>6,250</u>	<u>4,243</u>
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized; 22,597,144 and 22,382,340 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	23	22
Additional paid-in capital	193,194	189,830
Accumulated other comprehensive loss	(55)	—
Accumulated deficit	<u>(131,438)</u>	<u>(86,351)</u>
Total stockholders' equity	61,724	103,501
Total liabilities and stockholders' equity	<u>\$ 67,974</u>	<u>\$ 107,744</u>

The accompanying notes are an integral part of these consolidated financial statements.

Tokai Pharmaceuticals, Inc.

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,		
	2015	2014	2013
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	32,638	14,577	12,201
General and administrative	12,623	8,885	3,548
Total operating expenses	45,261	23,462	15,749
Loss from operations	(45,261)	(23,462)	(15,749)
Interest and other income (expense), net	174	166	24
Net loss	\$ (45,087)	\$ (23,296)	\$ (15,725)
Accretion of redeemable convertible preferred stock to redemption value	—	—	(94)
Net loss attributable to common stockholders	\$ (45,087)	\$ (23,296)	\$ (15,819)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.01)	\$ (3.60)	\$ (38.02)
Weighted average common shares outstanding, basic and diluted	22,484,343	6,469,289	416,037
Comprehensive loss:			
Net loss	\$ (45,087)	\$ (23,296)	\$ (15,725)
Other comprehensive loss:			
Unrealized loss on marketable securities	(55)	—	—
Total other comprehensive loss	(55)	—	—
Total comprehensive loss	\$ (45,142)	\$ (23,296)	\$ (15,725)

The accompanying notes are an integral part of these consolidated financial statements.

Tokai Pharmaceuticals, Inc.

Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)

	Series A, B-1, B-2, C, D-1, D-2, D-3 and E Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2012	98,693,750	\$ 49,845	464,633	\$ —	\$ 7,429	\$ —	\$ (47,330)	\$ (39,901)
Issuance of Series E redeemable convertible preferred stock, net of issuance costs of \$94	56,892,391	35,406	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	157,804	—	215	—	—	215
Repurchase and forfeiture of unvested restricted stock	—	—	(129,145)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	238	—	—	238
Accretion of Series E redeemable convertible preferred stock to redemption value	—	94	—	—	(94)	—	—	(94)
Net loss	—	—	—	—	—	—	(15,725)	(15,725)
Balances at December 31, 2013	155,586,141	85,345	493,292	—	7,788	—	(63,055)	(55,267)
Issuance of common stock upon exercise of stock options	—	—	8,875	—	16	—	—	16
Stock-based compensation expense	—	—	—	—	2,108	—	—	2,108
Conversion of preferred stock to common stock	(155,586,141)	(85,345)	14,860,173	15	85,330	—	—	85,345
Issuance of common stock upon initial public offering	—	—	7,020,000	7	97,922	—	—	97,929
Issuance costs	—	—	—	—	(3,334)	—	—	(3,334)
Net loss	—	—	—	—	—	—	(23,296)	(23,296)
Balances at December 31, 2014	—	—	22,382,340	22	189,830	—	(86,351)	103,501
Issuance of common stock upon exercise of stock options	—	—	201,153	1	463	—	—	464
Issuance of common stock upon vesting of restricted stock units	—	—	13,651	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,901	—	—	2,901
Unrealized loss on marketable securities	—	—	—	—	—	(55)	—	(55)
Net loss	—	—	—	—	—	—	(45,087)	(45,087)
Balances at December 31, 2015	—	\$ —	22,597,144	\$ 23	\$ 193,194	\$ (55)	\$ (131,438)	\$ 61,724

The accompanying notes are an integral part of these consolidated financial statements.

Tokai Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net loss	\$ (45,087)	\$ (23,296)	\$(15,725)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	2,901	2,108	238
Depreciation expense	109	21	10
Release of reserve for loan to former advisor	(49)	(158)	—
Premium on purchase of marketable securities	(186)	—	—
Amortization of premium on marketable securities	72	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(958)	(1,830)	(190)
Accounts payable	443	760	(759)
Accrued expenses	1,476	1,274	950
Other assets	(45)	—	—
Other long-term liabilities	88	—	—
Net cash used in operating activities	<u>(41,236)</u>	<u>(21,121)</u>	<u>(15,476)</u>
Cash flows from investing activities:			
Purchases of marketable securities	(39,875)	—	—
Purchases of property and equipment	(565)	(25)	(23)
Change in restricted cash	(70)	(150)	(30)
Net cash used in investing activities	<u>(40,510)</u>	<u>(175)</u>	<u>(53)</u>
Cash flows from financing activities:			
Repayment of notes receivable	49	158	—
Proceeds from exercise of common stock options	464	16	215
Proceeds from initial public offering, net of underwriting discounts and commissions	—	97,929	—
Payments of initial public offering costs	—	(3,304)	(30)
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	—	35,406
Net cash provided by financing activities	<u>513</u>	<u>94,799</u>	<u>35,591</u>
Net increase (decrease) in cash and cash equivalents	(81,233)	73,503	20,062
Cash and cash equivalents at beginning of period	<u>105,256</u>	<u>31,753</u>	<u>11,691</u>
Cash and cash equivalents at end of period	<u>\$ 24,023</u>	<u>\$ 105,256</u>	<u>\$ 31,753</u>
Supplemental disclosure of non-cash investing and financing activities:			
Conversion of redeemable convertible preferred stock to common stock	\$ —	\$ (85,345)	\$ —
Accretion of redeemable convertible preferred stock to redemption value	\$ —	\$ —	\$ 94

The accompanying notes are an integral part of these consolidated financial statements.

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

1. Nature of the Business and Basis of Presentation

Tokai Pharmaceuticals, Inc. (the “Company”) was incorporated on March 26, 2004 under the laws of the State of Delaware. The Company is a biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of prostate cancer and other hormonally-driven diseases. The Company’s lead drug candidate, galeterone, is an oral small molecule that utilizes the mechanistic pathways of current second-generation androgen signaling inhibitors, while also introducing a distinct third mechanism— androgen receptor degradation. The Company is developing galeterone for the treatment of patients with metastatic castration resistant prostate cancer (“mCRPC”). Since its inception, the Company has devoted substantially all of its efforts to research and development, in-licensing technology and raising capital.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Galeterone, which is currently under development, and any product candidates that the Company may seek to develop in the future, will require significant additional research and development efforts, including extensive preclinical and clinical testing, and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance capabilities.

There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary regulatory approval or that any approved products will be commercially viable. Even if the Company’s drug development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and contracted service providers.

On September 22, 2014, the Company completed an initial public offering (“IPO”) of its common stock through the issuance and sale of 6,480,000 shares of common stock at a price to the public of \$15.00 per share, resulting in net proceeds of \$87,062 after deducting underwriting discounts and commissions and offering expenses. Upon the closing of the IPO, all outstanding shares of the Company’s redeemable convertible preferred stock automatically converted into 14,860,173 shares of the Company’s common stock. On October 9, 2014, the Company issued and sold an additional 540,000 shares of its common stock at the public offering price of \$15.00 per share as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock, resulting in additional net proceeds to the Company of \$7,533 after deducting underwriting discounts and commissions.

The Company’s consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business. The Company has incurred losses and negative cash flows from operations since inception. As of December 31, 2015, the Company had an accumulated deficit of \$131,438 and had cash and investments of \$63,957. The Company believes its cash and investments balance as of December 31, 2015 will only be sufficient to enable it to fund planned operating expenses and capital expenditure requirements into the first half of 2017. The Company will need to obtain substantial additional funding in order to complete the development of, and to commercialize, galeterone for patients with AR-V7 positive mCRPC and in other indications and patient populations, submit an NDA to the FDA for galeterone, conduct other clinical trials of galeterone, and develop or commercialize any future product candidates. If the Company is unable to raise capital when needed or on acceptable terms, it may

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

be forced to delay, reduce, terminate or eliminate its product development programs and commercialization efforts. The Company's ability to generate product revenue and operating cash flow will depend heavily on the successful development and eventual commercialization of galeterone and other product candidates that it may develop in the future.

The accompanying consolidated financial statements and footnotes include Diotima Pharmaceuticals, Inc. ("Diotima"), a variable interest entity in which the Company had a variable financial interest and was the primary beneficiary but had no ownership interest. In 2010, the Company formed and incorporated Diotima. Diotima operated as a stand-alone company with limited activity through April 2014. In early 2014, the license agreements relating to the Diotima compounds were terminated. Additionally, in April 2014, the board of directors and stockholders of Diotima approved the dissolution of Diotima, and Diotima was dissolved. All significant intercompany balances and transactions between the Company and Diotima have been eliminated in consolidation. Expenses incurred by Diotima for the years ended December 31, 2014 and 2013 were \$8 and \$60, respectively.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates, assumptions and judgments reflected in these consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of ninety days or less at date of purchase to be cash equivalents. Cash equivalents, which consist of money market accounts, are stated at fair value.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive loss in stockholders' equity (deficit). Realized gains and losses and declines in value judged to be other than temporary are included as a component of interest and other income (expense), net based on the specific identification method. The Company has classified its marketable securities with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities are available for current operations.

Concentration of Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company has all cash and cash equivalents and marketable securities' balances at two accredited financial institutions, in amounts that exceed federally

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and formulated drugs.

The Company is dependent on Qiagen Manchester Limited (“Qiagen”) to develop and commercialize a companion diagnostic test for use with galeterone to identify mCRPC patients with the AR-V7 splice variant. If Qiagen is unable to successfully develop and commercialize the companion diagnostic test, the development, approval and commercialization of galeterone could be adversely affected.

Fair Value Measurements

Certain assets and liabilities are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method based upon estimated useful life as follows:

Lab equipment	3 years
Computer equipment	3 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of life of lease or estimated useful life

Upon retirement or sale of property and equipment, the cost and related accumulated depreciation of such property and equipment disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Research and Development Costs

Research and development costs are expensed as incurred. Included in research and development expenses are salaries, stock-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company's research and development activities, including manufacturing expenses and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials. The Company expenses raw materials used to manufacture its drug substance when received.

As part of the process of preparing consolidated financial statements, the Company is required to estimate its accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with company personnel and outside vendors to identify services that have been performed on the Company's behalf and estimating the level of service performed and the associated costs incurred for the services when the Company has not yet been invoiced or otherwise notified of the actual costs. The majority of the Company's service providers invoice in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. The Company makes estimates of its accrued expenses as of each balance sheet date in its consolidated financial statements based on facts and circumstances known to the Company at that time. Examples of estimated accrued research and development expenses include fees paid to:

- clinical research organizations in connection with clinical trials;
- investigative sites or other providers in connection with clinical trials;
- Qiagen in connection with the development of the AR-V7 clinical trial assay and companion diagnostic test;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple clinical research organizations and investigative sites that manage and conduct clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or amount of prepaid expense accordingly. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low in any particular period. For the years ended December 31, 2015, 2014 and 2013, the Company has not made any material adjustments to its prior estimates of accrued research and development expenses.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors at the fair value on the date of the grant using the Black-Scholes option-pricing model. The fair value of the awards is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions, while the graded vesting method is applied to all grants with both service and performance conditions. For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of the unvested portion of the awards is re-measured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in its consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

As of December 31, 2015, the Company has early adopted Accounting Standards Update 2015-17, *Balance Sheet Classification of Deferred Taxes*, issued by the Financial Accounting Standards Board (the "FASB") in November 2015, which simplifies the presentation of deferred income taxes by eliminating the need for entities to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. The Company adopted this guidance retrospectively to all periods presented. As the Company had no current deferred tax assets or current tax liabilities on its consolidated balance sheet, the adoption of this guidance had no impact on the Company's financial statements.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. No revenue has been generated since inception. The Company holds tangible assets with a net book value of \$175 in laboratories located outside of the United States.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the year ended December 31, 2015, the Company's only element of other comprehensive loss was unrealized loss on marketable securities. For the years ended December 31, 2014 and 2013, there was no difference between net loss and comprehensive loss.

Net Income (Loss) Per Share

In September 2014, upon the closing of the IPO, all of the outstanding shares of the Company's redeemable convertible preferred stock automatically converted into 14,860,173 shares of the Company's common stock. Prior to this conversion, the Company followed the two-class method when computing net income (loss) per share as the Company had issued shares that met the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company's redeemable convertible preferred stock contractually entitled the holders of

Tokai Pharmaceuticals, Inc.**Notes to Consolidated Financial Statements**
(amounts in thousands, except share and per share amounts)

such shares to participate in dividends, but did not contractually require the holders of such shares to participate in losses of the Company. Accordingly, the two-class method did not apply for periods in which the Company reported a net loss or a net loss attributable to common stockholders resulting from dividends or accretion related to its redeemable convertible preferred stock.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common shares, as determined using the treasury stock method. For periods in which the Company has reported net losses, diluted net loss per common share attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The following common stock equivalents outstanding as of December 31, 2015, 2014 and 2013 were excluded from the computation of diluted net loss per share for the years ended December 31, 2015, 2014 and 2013, because they had an anti-dilutive impact:

	December 31,		
	2015	2014	2013
Stock options to purchase common stock	2,861,011	2,146,927	1,124,116
Restricted common stock units	40,953	54,604	—
Redeemable convertible preferred stock (as converted to common stock)	—	—	14,860,173
	<u>2,901,964</u>	<u>2,201,531</u>	<u>15,984,289</u>

Recently Issued Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40)*. The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. This guidance relates to footnote disclosure only and the adoption will not impact the Company's financial position, results of operations or liquidity.

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

3. Marketable Securities and Fair Value Measurements

As of December 31, 2015, marketable securities by security type consisted of:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Certificates of Deposit (due within one year)	\$ 13,709	\$ —	\$ —	\$ 13,709
Certificates of Deposit (due after one year through two years)	1,178	—	—	1,178
United States Treasury Notes (due within one year)	22,596	—	(47)	22,549
United States Treasury Notes (due after one year through two years)	2,506	—	(8)	2,498
Total	<u>\$ 39,989</u>	<u>\$ —</u>	<u>\$ (55)</u>	<u>\$ 39,934</u>

The Company did not have marketable securities as of December 31, 2014.

The following tables present the Company's fair value hierarchy for its cash equivalents and marketable securities, which are measured at fair value on a recurring basis as of December 31, 2015 and 2014:

Fair Value Measurements at December 31, 2015

	<u>Using</u>			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Cash equivalents:				
Money Market Instruments	\$ —	\$ 18,361	\$ —	\$ 18,361
Marketable securities:				
Certificates of Deposit	—	14,887	—	14,887
United States Treasury Notes	—	25,047	—	25,047
Total	<u>\$ —</u>	<u>\$ 58,295</u>	<u>\$ —</u>	<u>\$ 58,295</u>

Fair Value Measurements at December 31, 2014

	<u>Using</u>			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Cash equivalents:				
Money Market Instruments	\$ —	\$ 91,316	\$ —	\$ 91,316
Total	<u>\$ —</u>	<u>\$ 91,316</u>	<u>\$ —</u>	<u>\$ 91,316</u>

The carrying values of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Tokai Pharmaceuticals, Inc.**Notes to Consolidated Financial Statements**
(amounts in thousands, except share and per share amounts)**4. Property and Equipment, net**

Property and equipment, net consisted of the following as of December 31, 2015 and 2014:

	December 31,	
	2015	2014
Lab equipment	\$ 322	\$ —
Computer equipment	243	91
Leasehold improvements	66	—
Furniture and fixtures	23	—
	<u>654</u>	<u>91</u>
Less: Accumulated depreciation	<u>(165)</u>	<u>(58)</u>
	<u>\$ 489</u>	<u>\$ 33</u>

Depreciation expense was \$109, \$21 and \$10 for the years ended December 31, 2015, 2014 and 2013, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2015 and 2014:

	December 31,	
	2015	2014
Accrued research and development expenses	\$3,188	\$1,853
Accrued payroll and related expenses	900	963
Accrued professional fees	699	497
Accrued other	167	165
	<u>\$4,954</u>	<u>\$3,478</u>

6. Redeemable Convertible Preferred Stock

Prior to the completion of its IPO in September 2014 (Note 7), the Company had outstanding Series A, Series B-1, Series B-2, Series C, Series D-1, Series D-2, Series D-3 and Series E redeemable convertible preferred stock (collectively, the "Redeemable Preferred Stock"). The Company classified the Redeemable Preferred Stock outside of stockholders' equity (deficit) because the shares contained redemption features that were not solely within the Company's control. In connection with the closing of the Company's IPO, all of the Company's outstanding Redeemable Preferred Stock automatically converted into common stock on a 10.47-for-1 basis. No Redeemable Preferred Stock was outstanding as of December 31, 2014 or 2015.

In May and October 2013, the Company issued an aggregate of 56,892,391 shares of Series E redeemable convertible preferred stock to existing and new investors at \$0.62398475 per share for gross proceeds of \$35,500. The Company incurred issuance costs of \$94 in connection with the sale and issuance of these shares of Series E redeemable convertible preferred stock which were immediately accreted to the carrying value of the Series E redeemable convertible preferred stock.

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

7. Common Stock

On August 29, 2014, the Company effected a 1-for-10.47 reverse stock split of its issued and outstanding shares of common stock. Accordingly, all share and per share amounts for all periods presented in these consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split.

On September 22, 2014, the Company completed an IPO of its common stock through the issuance and sale of 6,480,000 shares of common stock at a price to the public of \$15.00 per share, resulting in net proceeds of \$87,062 after deducting underwriting discounts and commissions and offering expenses. Upon the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock automatically converted into 14,860,173 shares of the Company's common stock. On October 9, 2014, the Company issued and sold an additional 540,000 shares of its common stock at the public offering price of \$15.00 per share as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock, resulting in additional net proceeds to the Company of \$7,533 after deducting underwriting discounts and commissions.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

8. Stock-Based Awards

The Company's 2014 Stock Incentive Plan (the "2014 Plan") permits the Company to make grants of incentive stock options, non-statutory stock options, restricted stock, restricted stock units, stock appreciation rights and other stock-based awards to the Company's employees, officers, directors, consultants and advisors; however, incentive stock options may only be granted to the Company's employees. The number of shares initially reserved for issuance under the 2014 Plan was 1,745,413 shares of common stock and may be increased by the number of shares under the 2007 Stock Incentive Plan (the "2007 Plan") that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company. The number of shares of common stock that may be issued under the plan is also subject to an annual increase on the first day of each fiscal year equal to the lesser of (i) 1,800,000 shares of the Company's common stock, (ii) 4% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year or (iii) an amount determined by the Company's board of directors. As of December 31, 2015, 1,156,154 shares remained available for issuance under the 2014 Plan. The number of authorized shares reserved for issuance under the 2014 Plan was increased by 903,885 shares effective as of January 1, 2016.

As required by the 2007 Plan and 2014 Plan, the exercise price for stock options granted is not to be less than the fair value of common stock as of the date of grant. The Company bases fair value of common stock on the quoted market price. Prior to the IPO, the value of common stock was determined by the Company's board of directors by taking into consideration its most recently available valuation of common stock performed by management and the board of directors as well as additional factors which might have changed since the date of the most recent contemporaneous valuation through the date of grant.

During the years ended December 31, 2015, 2014 and 2013, the Company granted options to purchase 996,845, 1,039,155 and 786,537 shares of common stock, respectively, to certain employees, consultants and directors. The vesting of most of these awards is time-based and the restrictions typically lapse over three to four years.

Tokai Pharmaceuticals, Inc.**Notes to Consolidated Financial Statements**
(amounts in thousands, except share and per share amounts)***2014 Employee Stock Purchase Plan***

Under the 2014 Employee Stock Purchase Plan (the “ESPP”), an aggregate of 225,000 shares of the Company’s common stock are reserved for issuance. The number of shares of the Company’s common stock reserved for issuance under the ESPP will automatically increase on the first day of each fiscal year equal to the lesser of (1) 450,000 shares of the Company’s common stock, (2) 1% of the total number of shares of the Company’s common stock outstanding on the first day of the applicable fiscal year and (3) an amount determined by the Company’s board of directors. No offering periods have commenced under the ESPP and the number of shares reserved for issuance under the ESPP have not increased.

Stock Option Valuation

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to its IPO, the Company was a private company and lacked company-specific historical and implied volatility information. Therefore, the Company estimated its expected stock volatility based on the historical volatility of a publicly traded group of peer companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company’s stock options has been determined utilizing the “simplified” method for awards that qualify as “plain-vanilla” options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table sets forth the assumptions that the Company used to determine the fair value of the stock options granted, presented on a weighted average basis:

	Year Ended December 31,		
	2015	2014	2013
Risk-free interest rate	1.79%	1.83%	1.72%
Expected term (in years)	6.01	5.95	5.98
Expected volatility	74.2%	79.4%	79.7%
Expected dividend yield	0%	0%	0%

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

The following table summarizes the Company's stock option activity from January 1, 2015 through December 31, 2015:

	<u>Shares Issuable Under Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (In years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding as of December 31, 2014	2,146,927	\$ 5.54	8.6	\$ 19,802
Granted	996,845	10.60		
Exercised	(201,153)	2.31		
Forfeited	(81,608)	4.27		
Outstanding as of December 31, 2015	<u>2,861,011</u>	\$ 7.57	8.3	\$ 7,906
Options vested and expected to vest as of December 31, 2015	2,822,786	\$ 7.52	8.2	\$ 7,896
Options exercisable as of December 31, 2015	1,199,676	\$ 4.10	7.0	\$ 6,455

The aggregate intrinsic value was calculated based on the positive differences between the market value of the Company's common stock on December 31, 2015 and 2014, of \$8.72 and \$14.74 per share, respectively, and the exercise prices of the options.

The weighted average grant date fair value of stock options granted was \$6.94, \$6.70 and \$1.17 per share for the years ended December 31, 2015, 2014 and 2013, respectively.

The total intrinsic value of stock options exercised was \$2,236, \$35 and \$33 for the years ended December 31, 2015, 2014 and 2013, respectively.

Restricted Common Stock Units

The 2014 Plan provides for the award of restricted common stock units. The Company has granted restricted common stock units with time-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award.

The table below summarizes the Company's restricted stock unit activity from January 1, 2015 through December 31, 2015:

	<u>Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested restricted common stock units as of December 31, 2014	54,604	\$ 15.00
Issued	—	—
Vested	(13,651)	15.00
Forfeited	—	—
Unvested restricted common stock units as of December 31, 2015	<u>40,953</u>	\$ 15.00

Tokai Pharmaceuticals, Inc.**Notes to Consolidated Financial Statements**
(amounts in thousands, except share and per share amounts)

During 2014, the Company granted 54,604 restricted stock units with a fair value of \$15.00 per share that are subject to time-based vesting conditions that lapse over four years. Upon vesting, the restricted stock units entitle the holder to one share of common stock for each restricted stock unit. All restricted stock units currently granted have been classified as equity instruments as their terms require settlement in shares. Restricted stock units with time-based vesting conditions are valued on the grant date using the grant date market price of the underlying shares. As of December 31, 2015, the Company estimates that all shares of restricted stock units with an intrinsic value of \$357 and a weighted average remaining contractual term of 2.67 years will ultimately vest. The Company did not grant restricted stock units in 2015 or 2013.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted common stock units in the following expense categories of its statements of operations:

	Year Ended December 31,		
	2015	2014	2013
Research and development	\$ 634	\$ 552	\$ 91
General and administrative	2,267	1,556	147
	<u>\$ 2,901</u>	<u>\$ 2,108</u>	<u>\$ 238</u>

Stock-based compensation expense for the year ended December 31, 2014 includes \$880 of stock-based compensation expense related to a performance-based option grant which vested during 2014.

As of December 31, 2015, the Company had an aggregate of \$10,738 of unrecognized stock-based compensation expense, which it expects to recognize over a weighted average period of 3.06 years.

9. Commitments and Contingencies**Leases**

In February 2015, the Company entered into a sublease with a Massachusetts limited liability company (the "sublandlord") for 15,981 square feet of office space in Boston, Massachusetts. The sublease is subject and subordinate to a prime lease, dated October 5, 2010, between the sublandlord and the prime landlord. The term of the sublease commenced on April 1, 2015 and expires on December 31, 2016. If the term of the prime lease is terminated for any reason prior to the expiration or earlier termination of the sublease, the sublease will terminate immediately and the Company will have no recourse against the sublandlord for such termination. In June 2015, the Company entered into a lease for the existing space with the prime landlord (the "landlord") which effectively extends the term of the lease of the existing space until July 31, 2018. Payment escalations specified in the lease agreements are accrued such that rent expense per square foot is recognized on a straight-line basis over the terms of occupancy.

Prior to April 2015, the Company leased office space in Cambridge, Massachusetts, and obtained certain office-related services on a month-to-month basis under a 30-day cancelable operating service agreement. The Company recorded exit costs of \$133 included in rent expense during the year ended December 31, 2015 in connection with the termination of the Cambridge lease.

During the years ended December 31, 2015, 2014 and 2013, the Company recognized \$835, \$520 and \$366, respectively, of rental expense related to office space.

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

As of December 31, 2015, future minimum lease payments under noncancelable office leases are as follows:

2016	\$ 555
2017	839
2018	489
	<u>\$1,883</u>

Restricted Cash and Letters of Credit

As of December 31, 2015 and 2014, the Company held a money market account to collateralize a credit card account with its bank of \$200, which was classified as restricted cash on the consolidated balance sheet as of December 31, 2015 and 2014. In connection with the new office lease entered into in 2015, the Company was required to maintain a letter of credit totaling \$70 for the benefit of the landlord of the new lease. The landlord can draw against the letter of credit in the event of default by the Company. The Company holds \$70 in a money market account to collateralize the letter of credit, which amount is also included in restricted cash on the balance sheet as of December 31, 2015.

Intellectual Property Licenses

The Company has a master license agreement with the University of Maryland, Baltimore (“UMB”). Pursuant to the license agreement, UMB granted an exclusive, worldwide license, with the right to sublicense, under certain patents and patent applications to make, have made, use, sell, offer to sell and import certain anti-androgen steroids, including galeterone, for the prevention, diagnosis, treatment or control of any human or animal disease. In addition, UMB granted the Company a first option to receive an exclusive license to UMB’s rights in certain improvements to the licensed products. The Company has exercised its option and acquired exclusive rights to licensed improvements under three amendments to the license agreement. The Company is obligated to pay UMB an annual maintenance fee of \$10 each year until the first commercial sale of a product developed using the licensed technology. The Company is also obligated to make an additional \$50 milestone payment to UMB for each additional investigational new drug application filed for a licensed product and a \$100 milestone payment upon the approval by the U.S. Food and Drug Administration of each new drug application (“NDA”) for a licensed product. Because none of these milestones have been achieved as of December 31, 2015, no liabilities for such milestone payments have been recorded in the Company’s consolidated financial statements.

The Company must also pay UMB a low-single digit percentage royalty on aggregate worldwide net sales of licensed products, including sales by sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. The royalty obligations are subject to specified reductions in the event that additional licenses need to be obtained from third parties or in the event of specified competition from third-party products licensed by UMB. Minimum annual royalty payments to UMB are \$50 beginning in the year following the year in which the first commercial sale occurs. The Company must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, the Company is responsible for all patent expenses related to the prosecution and maintenance of the licensed patents. As of December 31, 2015, the Company has not yet developed a commercial product using the licensed technologies, nor has it entered into any sublicense agreements for the technologies.

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

In January 2015, the Company entered into an exclusive license agreement with The Johns Hopkins University (“Johns Hopkins”) pursuant to which Johns Hopkins granted the Company an exclusive, worldwide license under certain patents and patent applications, and a non-exclusive license under certain know-how, in each case with the right to sublicense, to make, have made, use, sell, offer to sell and import certain assays to identify androgen receptor variants for use as a companion diagnostic with galeterone. In addition, Johns Hopkins granted the Company an option to negotiate an exclusive license to Johns Hopkins’s rights in certain improvements to the licensed intellectual property.

Under the terms of the license agreement, the Company is obligated to diligently develop, manufacture and sell licensed products. The Company is also obligated to use commercially reasonable efforts to achieve specified milestone events by specified dates. Unless the license agreement with Johns Hopkins is terminated earlier as provided below, the license from Johns Hopkins expires on a country-by-country basis as of the later of the expiration date of the last to expire of the claims of the patent rights licensed under the agreement in such country or ten years after the first commercial sale of a licensed product in such country. Johns Hopkins may terminate the agreement if the Company fails to achieve such milestone events and does not cure such failure within a specified termination notice period. Johns Hopkins may also terminate the agreement upon a material breach by the Company under the agreement if the Company does not cure such breach within a specified notice period or upon the Company’s bankruptcy or insolvency. The Company may terminate the agreement at any time upon 90 days’ notice.

In consideration for the rights granted to the Company under the license agreement, the Company made an upfront payment to Johns Hopkins of \$75 following the execution of the license agreement, which was recognized as research and development expense during the year ended December 31, 2015. The Company is obligated to pay Johns Hopkins an annual minimum royalty of up to \$30 and to make milestone payments to Johns Hopkins upon the achievement of specified technical and commercial milestones. If all such milestones were achieved, the total milestone payments owed to Johns Hopkins would equal \$700 in the aggregate. During the year ended December 31, 2015, the Company expensed \$50 related to the achievement of two of these milestones. The Company has not achieved any other milestones and therefore no additional liabilities for such milestone payments have been recorded in the Company’s consolidated financial statements.

The Company must also pay Johns Hopkins single digit percentage royalties on aggregate worldwide net sales of licensed products (but not galeterone), including sales by sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. These royalty obligations are subject to specified reductions in the event that additional licenses from third parties are required. The Company must also pay Johns Hopkins 20% of all non-royalty sublicense income received from sublicensees and reimburse Johns Hopkins for patent costs. As of December 31, 2015, the Company has not yet developed a commercial product using the licensed technologies.

Companion Diagnostic Development Agreement

In March 2015, the Company entered into a project work plan with Qiagen under a Master Collaboration Agreement, dated January 12, 2015, between the Company and Qiagen (together with the project work plan, the “CDx Agreement”). Pursuant to the CDx Agreement, Qiagen has agreed to develop and commercialize a companion diagnostic test for use with galeterone to identify mCRPC patients with the AR-V7 splice variant. Qiagen has also developed under the CDx Agreement a clinical trial assay for use in our pivotal Phase 3 clinical trial of galeterone in order to identify mCRPC patients whose tumor cells express AR-V7.

Tokai Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

Under the CDx Agreement, Qiagen is responsible for developing, and obtaining and maintaining regulatory approvals for the companion diagnostic test in the United States, the European Union, Canada, Australia and such other countries as the parties may agree. In addition, Qiagen has agreed to use commercially reasonable and diligent efforts to manufacture the companion diagnostic test and to make the companion diagnostic test commercially available in those countries in which the Company has obtained regulatory approval for, and has valid patent claims covering, galeterone. Qiagen will be responsible for commercializing the companion diagnostic in each such country. If Qiagen elects not to commercialize the companion diagnostic test itself in any such country, for so long as there are valid patent claims covering galeterone in such country, Qiagen has agreed to procure alternative distribution channels or otherwise supply the companion diagnostic test to the Company in order for the Company to market galeterone in combination with the companion diagnostic test. Upon the request of the Company, the parties have also agreed to negotiate in good faith to expand the scope of the projects under the Agreement to, among other things, provide for the development and commercialization of the companion diagnostic test for use with galeterone in Japan.

Subject to the terms of the CDx Agreement, the Company paid Qiagen a fee for the exclusive right to have the circulating tumor cell enrichment technology used in the development of the companion diagnostic test, which was recognized as research and development expense during the year ended December 31, 2015. The Company will also pay Qiagen fees for the development of the AR-V7 clinical trial assay and a contingent milestone payment of \$1,000 upon Qiagen obtaining pre-market approval of the companion diagnostic test. Furthermore, the Company will reimburse Qiagen for certain direct out-of-pocket costs incurred by Qiagen, including for sample material. These amounts are subject to adjustment if the parties determine that changes in the scope of the development program are required. Following commercialization, the Company will have no further payment obligations to Qiagen under the Agreement. The Company will not, however, receive any revenues from future sales, if any, of the companion diagnostic test.

The CDx Agreement expires on the later to occur of (i) the fifth anniversary of regulatory approval of the companion diagnostic test and (ii) the expiration of Qiagen's commercialization obligations under the CDx Agreement. The Company is permitted to terminate the CDx Agreement for convenience upon 180 days' written notice to Qiagen. Either party may terminate the CDx Agreement upon 60 days' written notice to the other party based on uncured material breaches by the other party and may terminate the CDx Agreement immediately based on the bankruptcy or insolvency of the other party.

Advisor Agreement

The Company paid a financial advisor \$1,053 upon the closing of its IPO in connection with strategic and financial advisory services unrelated to the offering. The Company recorded this amount as general and administrative expense in its consolidated statement of operations and comprehensive loss for the year ended December 31, 2014.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers, which provide, among other things, that the Company will indemnify such directors and executive officers to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer. The maximum potential amount of future payments the Company could be required to make under these

Tokai Pharmaceuticals, Inc.**Notes to Consolidated Financial Statements**
(amounts in thousands, except share and per share amounts)

indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of the indemnification agreements described above. In addition, the Company maintains directors and officers insurance coverage. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2015.

10. Income Taxes

During the years ended December 31, 2015, 2014 and 2013, the Company recorded no income tax benefits for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2015	2014	2013
Federal statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
Federal research and development tax credit	(0.5)	(0.9)	(0.7)
State taxes, net of federal benefit	(5.3)	(4.5)	(5.6)
Stock-based compensation expense	0.4	1.1	0.4
Other	0.1	0.2	0.1
Increase in deferred tax asset valuation allowance	39.3	38.1	39.8
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

Net deferred tax assets as of December 31, 2015 and 2014 consisted of the following:

	December 31,	
	2015	2014
Deferred tax assets:		
Capitalized research and development expenses	\$ 37,765	\$ 24,945
Net operating loss carryforwards	10,224	6,292
Stock-based compensation	1,371	612
Research and development tax credit carryforwards	1,273	1,008
Accrued expenses	339	414
Other	56	1
Total gross deferred tax assets	51,028	33,272
Valuation allowance	(51,028)	(33,272)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Tokai Pharmaceuticals, Inc.**Notes to Consolidated Financial Statements**
(amounts in thousands, except share and per share amounts)

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2015, 2014 and 2013 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,		
	2015	2014	2013
Valuation allowance as of beginning of year	\$33,272	\$24,402	\$18,138
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	17,756	8,870	6,264
Valuation allowance as of end of year	<u>\$51,028</u>	<u>\$33,272</u>	<u>\$24,402</u>

As of December 31, 2015, the Company had net operating loss carryforwards for federal and state income tax purposes of \$27,900 and \$24,200, respectively, which begin to expire in 2024 and 2030, respectively. As of December 31, 2015, the federal and state net operating loss carryforwards include \$1,400 of deductions for stock option compensation for which the associated tax benefit will be credited to additional paid-in capital when realized. This amount is accounted for separately and is not included in the Company's deferred tax assets. As of December 31, 2015, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of \$1,040 and \$353, respectively, which begin to expire in 2025 and 2023, respectively. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code") due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. The Company has not conducted a formal study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382 of the Code, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards may be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2015 and 2014. Management reevaluates the positive and negative evidence at each reporting period.

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2015 or 2014.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from 2012 to the present. Earlier years may be examined to the extent that tax credit or net

Tokai Pharmaceuticals, Inc.**Notes to Consolidated Financial Statements**
(amounts in thousands, except share and per share amounts)

operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

11. 401(k) Plan

The Company has a 401(k) plan available for participating employees who meet certain eligibility requirements. Eligible employees may defer a portion of their salary as defined by the plan. Company contributions to the plan may be made at the discretion of the Board of Directors. To date, the Company has not made any contributions to the plan. Effective January 1, 2016, the Company has elected to make matching contributions for the plan year ending December 31, 2016 at a rate of 100% of each employee's contribution up to a maximum matching contribution of 3% of the employee's compensation and at a rate of 50% of each employee's contribution in excess of 3% up to a maximum of 5% of the employee's compensation.

12. Related Party Transactions

The Company had an outstanding loan to a former advisor comprised of unpaid principal and interest in the amount of \$220 that was deemed uncollectable and as a result, was fully reserved for in 2007. In 2014, the Company started to receive repayment of this note. This loan was fully repaid in April 2015. The Company recorded \$49 and \$158 for the years ended December 31, 2015 and 2014, respectively, in interest and other income (expense), net, representing cash collected during those periods.

13. Selected Quarterly Financial Data (Unaudited)

	Three Months Ended							
	Dec. 31, 2015	Sept. 30, 2015	June 30, 2015	March 31, 2015	Dec. 31, 2014	Sept. 30, 2014	June 30, 2014	March 31, 2014
Statement of Operations Data:								
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Loss from operations	(11,072)	(11,907)	(8,982)	(13,300)	(6,261)	(6,424)	(5,885)	(4,892)
Net loss	(11,017)	(11,853)	(8,957)	(13,260)	(6,208)	(6,390)	(5,851)	(4,847)
Basic and diluted net loss per share	\$ (0.49)	\$ (0.53)	\$ (0.40)	\$ (0.59)	\$ (0.28)	\$ (2.71)	\$ (11.68)	\$ (9.79)

Tokai Pharmaceuticals, Inc.

Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,630	\$ 24,023
Marketable securities	16,088	39,934
Prepaid expenses and other current assets	1,616	3,213
Total current assets	36,334	67,170
Property and equipment, net	117	489
Restricted cash	270	270
Other assets	—	45
Total assets	<u>\$ 36,721</u>	<u>\$ 67,974</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 886	\$ 1,208
Accrued expenses	5,458	4,954
Total current liabilities	6,344	6,162
Long-term liabilities	120	88
Total liabilities	6,464	6,250
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized; 22,641,651 and 22,597,144 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	23	23
Additional paid-in capital	195,891	193,194
Accumulated other comprehensive income (loss)	3	(55)
Accumulated deficit	(165,660)	(131,438)
Total stockholders' equity	30,257	61,724
Total liabilities and stockholders' equity	<u>\$ 36,721</u>	<u>\$ 67,974</u>

The accompanying notes are an integral part of these financial statements.

Tokai Pharmaceuticals, Inc.

Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	6,162	8,491	23,988	24,905
General and administrative	3,146	3,416	10,375	9,284
Total operating expenses	9,308	11,907	34,363	34,189
Loss from operations	(9,308)	(11,907)	(34,363)	(34,189)
Interest income and other income, net	38	54	141	119
Net loss	\$ (9,270)	\$ (11,853)	\$ (34,222)	\$ (34,070)
Net loss per share, basic and diluted	\$ (0.41)	\$ (0.53)	\$ (1.51)	\$ (1.52)
Weighted average common shares outstanding, basic and diluted	22,636,977	22,540,876	22,632,287	22,449,484
Comprehensive loss:				
Net loss	\$ (9,270)	\$ (11,853)	\$ (34,222)	\$ (34,070)
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities	(3)	10	58	8
Total other comprehensive income (loss)	(3)	10	58	8
Total comprehensive loss	\$ (9,273)	\$ (11,843)	\$ (34,164)	\$ (34,062)

The accompanying notes are an integral part of these financial statements.

Tokai Pharmaceuticals, Inc.

Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (34,222)	\$ (34,070)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,660	2,044
Depreciation expense	154	53
Impairment of property and equipment	235	—
Release of reserve for loan to former advisor	—	(49)
Premium on purchase of marketable securities	(2)	(186)
Amortization of premium on marketable securities	109	34
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,642	(1,507)
Accounts payable	(322)	887
Accrued expenses	504	429
Other assets	—	(45)
Other long-term liabilities	32	51
Net cash used in operating activities	<u>(29,210)</u>	<u>(32,359)</u>
Cash flows from investing activities:		
Proceeds from maturities of marketable securities	24,297	—
Purchases of marketable securities	(500)	(39,775)
Purchases of property and equipment	(17)	(349)
Change in restricted cash	—	(70)
Net cash provided by (used in) investing activities	<u>23,780</u>	<u>(40,194)</u>
Cash flows from financing activities:		
Repayment of notes receivable	—	49
Proceeds from exercise of common stock options	37	416
Net cash provided by financing activities	<u>37</u>	<u>465</u>
Net decrease in cash and cash equivalents	(5,393)	(72,088)
Cash and cash equivalents at beginning of period	24,023	105,256
Cash and cash equivalents at end of period	<u>\$ 18,630</u>	<u>\$ 33,168</u>
Supplemental disclosure of non-cash investing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ —	\$ 98

The accompanying notes are an integral part of these financial statements.

Tokai Pharmaceuticals, Inc.

Notes to Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

1. Nature of the Business and Basis of Presentation

Tokai Pharmaceuticals, Inc. (the “Company”) was incorporated on March 26, 2004 under the laws of the State of Delaware. The Company is a biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of prostate cancer and other hormonally-driven diseases. The Company’s lead drug candidate, galeterone, is an oral small molecule that utilizes the mechanistic pathways of current second-generation androgen signaling inhibitors, while also introducing a distinct third mechanism— androgen receptor degradation. Since its inception, the Company has devoted substantially all of its efforts to research and development, in-licensing technology and raising capital.

In July 2016, the Company announced its plan to discontinue the ARMOR3-SV Phase 3 clinical trial of galeterone following the recommendation made by the trial’s independent data monitoring committee (“DMC”). The Company anticipates that all patients enrolled in the ARMOR3-SV clinical trial will discontinue treatment by the end of this year. The Company is analyzing the unblinded data from the ARMOR3-SV clinical trial to evaluate potential paths forward for galeterone and its drug discovery program, known as the Androgen Receptor Degradation Agents (“ARDA”) program. Based on preliminary data reviewed to date, however, there is a substantial likelihood that the Company will not pursue the development of galeterone in AR-V7 positive metastatic castration resistant prostate cancer (“mCRPC”) in the future. Following the announcement regarding the discontinuation of the ARMOR3-SV trial, the Company reduced its workforce in the third quarter of 2016 by approximately 60% and incurred a charge of \$1,200 during the three months ended September 30, 2016 related to the workforce reduction including severance, benefits and related costs of which \$500 and \$700 were recorded in research and development expenses and general and administrative expenses, respectively. The Company paid \$300 of these costs during the three months ended September 30, 2016 and expects to pay \$600 in the fourth quarter of 2016 and \$300 in the first quarter of 2017. As of September 30, 2016, the Company had a balance of \$900 in accrued expenses related to these severance, benefits and related costs.

In addition, in August 2016, the Company determined to discontinue enrollment in its ongoing Phase 2 ARMOR2 expansion clinical trial of galeterone in mCRPC patients with acquired resistance to Xtandi® (enzalutamide) and not to proceed with the planned study of galeterone in mCRPC patients who rapidly progress on either enzalutamide or Zytiga® (abiraterone acetate). While no new patients are being enrolled in the ARMOR 2 trial, the Company is continuing to follow the patients who remain in the ARMOR2 trial.

In September 2016, the Company announced that the board of directors had initiated a review of strategic alternatives that could result in changes to its business strategy and future operations. The objective of this review, which is being conducted in parallel with the review of development options for galeterone and the ARDA program, is to maximize shareholder value.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Galeterone, which is currently under development, and any product candidates that the Company may seek to develop in the future under the ARDA program or otherwise, will require significant additional research and development efforts, including extensive preclinical and clinical testing, formulation development and manufacturing, and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance capabilities.

Tokai Pharmaceuticals, Inc.

Notes to Financial Statements

**(Amounts in thousands, except share and per share data)
(Unaudited)**

There can be no assurance that the Company's research and development activities will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary regulatory approval or that any approved products will be commercially viable. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and contracted service providers.

The Company's financial statements have been prepared on the basis of continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business. The Company has incurred losses and negative cash flows from operations since inception. As of September 30, 2016, the Company had an accumulated deficit of \$165,660 and had cash and investments of \$34,718. In light of the discontinuation of the ARMOR3-SV trial and the reduction in workforce that occurred in the third quarter of 2016 and assuming no new clinical efforts for galeterone or any other product candidate, the Company expects its cash and investments as of September 30, 2016 to be sufficient to fund operations for at least the next twelve months. The Company is currently evaluating potential paths forward for galeterone and its ARDA program and is reviewing strategic alternatives. If the Company determines to pursue an alternate strategy or engage in a strategic transaction, its future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by management. If the Company determines to further develop galeterone, proceed with its ARDA program, or both, substantial additional funding will be needed. Because of the significant uncertainty regarding its future plans, the Company is not able to accurately predict the impact of a potential change of the business strategy on future funding requirements. If the Company's cash and investments are not sufficient to fund a revised strategy and the Company is unable to raise capital when needed or on acceptable terms, the Company may be forced to delay, reduce, terminate or eliminate its product development programs and its commercialization efforts.

The balance sheet at December 31, 2015 was derived from audited financial statements, but does not include all disclosures required by U.S. generally accepted accounting principles ("GAAP"). The accompanying unaudited financial statements as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The Company believes, however, that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2015 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 10, 2016. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2016 and results of operations for the three and nine months ended September 30, 2016 and 2015 and cash flows for the nine months ended September 30, 2016 and 2015 have been made. The results of operations for the three and nine months ended September 30, 2016 and 2015 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2016.

Tokai Pharmaceuticals, Inc.**Notes to Financial Statements**
(Amounts in thousands, except share and per share data)
(Unaudited)**2. Summary of Significant Accounting Policies***Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates, assumptions and judgments reflected in these financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included as a component of interest income and other income, net based on the specific identification method. The Company classifies its marketable securities with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities are available for current operations.

At September 30, 2016, marketable securities by security type consisted of:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Certificates of Deposit (due within one year)	\$ 5,579	\$ —	\$ —	\$ 5,579
United States Treasury Notes (due within one year)	10,506	3	—	10,509
Total	<u>\$ 16,085</u>	<u>\$ 3</u>	<u>\$ —</u>	<u>\$ 16,088</u>

At December 31, 2015 marketable securities by security type consisted of:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
Certificates of Deposit (due within one year)	\$ 13,709	\$ —	\$ —	\$ 13,709
Certificates of Deposit (due after one year through two years)	1,178	—	—	1,178
United States Treasury Notes (due within one year)	22,596	—	(47)	22,549
United States Treasury Notes (due after one year through two years)	2,506	—	(8)	2,498
Total	<u>\$ 39,989</u>	<u>\$ —</u>	<u>\$ (55)</u>	<u>\$ 39,934</u>

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most

Tokai Pharmaceuticals, Inc.

Notes to Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The following tables present the Company's fair value hierarchy for its cash equivalents and marketable securities, which are measured at fair value on a recurring basis at September 30, 2016 and December 31, 2015:

	Fair Value Measurements at September 30, 2016 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money Market Instruments	\$ —	\$ 13,113	\$ —	\$ 13,113
Marketable securities:				
Certificates of Deposit	—	5,579	—	5,579
United States Treasury Notes	—	10,509	—	10,509
Total	<u>\$ —</u>	<u>\$ 29,201</u>	<u>\$ —</u>	<u>\$ 29,201</u>

	Fair Value Measurements at December 31, 2015 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money Market Instruments	\$ —	\$ 18,361	\$ —	\$ 18,361
Marketable securities:				
Certificates of Deposit	—	14,887	—	14,887
United States Treasury Notes	—	25,047	—	25,047
Total	<u>\$ —</u>	<u>\$ 58,295</u>	<u>\$ —</u>	<u>\$ 58,295</u>

The carrying values of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. Because the inclusion of common share equivalents in the calculation would be anti-dilutive for all periods presented, diluted net loss per share is the same as basic net loss per share.

Tokai Pharmaceuticals, Inc.
Notes to Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

The following common share equivalents outstanding as of September 30, 2016 and 2015 were excluded from the computation of diluted net loss per share for the three and nine months ended September 30, 2016 and 2015 because they had an anti-dilutive impact:

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Stock options to purchase common stock	2,117,531	2,861,011
Unvested restricted common stock units	—	40,953
	<u>2,117,531</u>	<u>2,901,964</u>

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40)*. The new guidance addresses management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Management’s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. This standard will be effective for fiscal years ending after December 15, 2016. Early adoption is permitted. This guidance relates to footnote disclosure only and its adoption will not impact the Company’s financial position, results of operations or liquidity.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (“ASU 2016-02”), which applies to all leases and will require lessees to put most leases on the balance sheet, but recognize expense in a manner similar to the current standard. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018. Early adoption is permitted. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited. The Company is evaluating this guidance.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation* (“ASU 2016-09”). ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. ASU 2016-09 will be effective for the first interim period within fiscal years beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on the Company’s financial position, results of operations and liquidity.

3. Accrued Expenses

Accrued expenses consisted of the following:

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
Accrued research and development expenses	\$ 3,565	\$ 3,188
Accrued payroll and related expenses	1,045	900
Accrued professional fees	734	699
Accrued other	114	167
	<u>\$ 5,458</u>	<u>\$ 4,954</u>

Tokai Pharmaceuticals, Inc.**Notes to Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)****4. Income Taxes**

The Company did not provide for any income taxes in the nine months ended September 30, 2016 or 2015. The Company had gross deferred tax assets of \$51,028 at December 31, 2015, which increased by approximately \$13,000 at September 30, 2016. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at each of September 30, 2016 and December 31, 2015, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

The Company has not recorded any amounts for unrecognized tax benefits as of September 30, 2016 or December 31, 2015. As of September 30, 2016 and December 31, 2015, the Company had no accrued interest or tax penalties recorded. The Company's income tax return reporting periods since December 31, 2012 are open to income tax audit examination by the federal and state tax authorities. In addition, because the Company has net operating loss carryforwards, the Internal Revenue Service is permitted to audit earlier years and propose adjustments up to the amount of net operating losses generated in those years.

5. Stock-Based Compensation

The Company grants stock-based awards under its 2014 Stock Incentive Plan and is authorized to issue, but has not issued as of September 30, 2016, common stock under its 2014 Employee Stock Purchase Plan. The Company also has outstanding stock options under its 2007 Stock Incentive Plan, but is no longer granting awards under this plan. As of September 30, 2016, 2,799,965 shares of common stock were available for issuance under the 2014 Stock Incentive Plan. As of September 30, 2016, 225,000 shares of common stock were available for issuance to participating employees under the 2014 Employee Stock Purchase Plan. The Company recorded stock-based compensation expense related to stock options and restricted common stock units in the following expense categories of its statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	\$ 93	\$ 156	\$ 498	\$ 464
General and administrative	553	648	2,162	1,580
	<u>\$ 646</u>	<u>\$ 804</u>	<u>\$ 2,660</u>	<u>\$ 2,044</u>

6. Commitments and Contingencies**Leases**

In February 2015, the Company entered into a sublease with a Massachusetts limited liability company (the "Sublandlord") for 15,981 square feet of office space in Boston, Massachusetts. The sublease is subject and subordinate to a prime lease between the Sublandlord and the prime landlord. The term of the sublease commenced on April 1, 2015 and expires on December 31, 2016. If the term of the prime lease is terminated for any reason prior to the expiration or earlier termination of the sublease, the sublease will terminate immediately and the Company will have no recourse against the Sublandlord for such termination. In June 2015, the Company entered into a lease (the "New Lease") for the existing space with the prime landlord (the "Landlord"), which effectively extends the term until July 31, 2018. Payment escalations specified in the lease agreements are accrued such that rent expense per square foot is recognized on a straight-line basis over the terms of occupancy.

Tokai Pharmaceuticals, Inc.

Notes to Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

Prior to April 2015, the Company leased office space in Cambridge, Massachusetts, and obtained certain office-related services on a month-to-month basis under a 30-day cancelable operating service agreement. The Company recorded exit costs of \$133 in connection with the termination of the Cambridge lease, which are included in rent expense during the nine months ended September 30, 2015.

During each of the three months ended September 30, 2016 and 2015, the Company recognized \$174 of rental expense related to office space. During the nine months ended September 30, 2016 and 2015, the Company recognized \$521 and \$661, respectively, of rental expense related to office space.

As of September 30, 2016, future minimum lease payments under noncancelable office leases were as follows:

Remainder of 2016	\$ 140
2017	839
2018	489
	<u>\$1,468</u>

Restricted Cash and Letters of Credit

The Company held a money market account of \$200 to collateralize a credit card account with its bank, which was classified as restricted cash on the balance sheet as of September 30, 2016 and December 31, 2015. The Company is required to maintain a letter of credit totaling \$70 for the benefit of the Landlord of the New Lease. The Landlord can draw against the letter of credit in the event of default by the Company. The Company held \$70 in a money market account to collateralize the letter of credit, which amount was also included in restricted cash on the balance sheet as of September 30, 2016 and December 31, 2015.

Intellectual Property Licenses

The Company has a master license agreement with the University of Maryland, Baltimore (“UMB”). Pursuant to the license agreement, UMB granted an exclusive, worldwide license, with the right to sublicense, under certain patents and patent applications to make, have made, use, sell, offer to sell and import certain anti-androgen steroids, including galeterone, for the prevention, diagnosis, treatment or control of any human or animal disease. In addition, UMB granted the Company a first option to receive an exclusive license to UMB’s rights in certain improvements to the licensed products. The Company has exercised its option and acquired exclusive rights to licensed improvements under four amendments to the license agreement. The Company is obligated to pay UMB an annual maintenance fee of \$10 each year until the first commercial sale of a product developed using the licensed technology. The Company is also obligated to make milestone payments of an additional \$50 for the filing of each additional investigational new drug application filed for a licensed product, aggregate milestone payments of up to \$150 associated with the development of a licensed product for a particular non-prostate disease indication, and a \$100 milestone payment upon the approval by the U.S. Food and Drug Administration (“FDA”) of each new drug application (“NDA”) for a licensed product. There were no milestones achieved during the nine months ended September 30, 2016 or 2015.

The Company must also pay UMB a low-single digit percentage royalty on aggregate worldwide net sales of licensed products, including sales by sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten

Tokai Pharmaceuticals, Inc.

Notes to Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

years after first commercial sale of the applicable licensed product, in each case in the applicable country. The royalty obligations are subject to specified reductions in the event that additional licenses need to be obtained from third parties or in the event of specified competition from third-party products licensed by UMB. Minimum annual royalty payments to UMB are \$50 beginning in the year following the year in which the first commercial sale occurs. The Company must also pay UMB 10% of all non-royalty sublicense income received from sublicensees. Finally, the Company is responsible for all patent expenses related to the prosecution and maintenance of the licensed patents. As of September 30, 2016 the Company has not yet developed a commercial product using the licensed technologies, nor has it entered into any sublicense agreements for the technologies.

In January 2015, the Company entered into an exclusive license agreement with The Johns Hopkins University (“Johns Hopkins”) pursuant to which Johns Hopkins granted the Company an exclusive, worldwide license under certain patents and patent applications, and a non-exclusive license under certain know-how, in each case with the right to sublicense, to make, have made, use, sell, offer to sell and import certain assays to identify androgen receptor variants for use as a companion diagnostic with galeterone. In addition, Johns Hopkins granted the Company an option to negotiate an exclusive license to Johns Hopkins’s rights in certain improvements to the licensed intellectual property.

In consideration for the rights granted to the Company under the license agreement, the Company made an upfront payment to Johns Hopkins of \$75 following the execution of the license agreement, which was recognized as research and development expense during the nine months ended September 30, 2015. The Company is obligated to pay Johns Hopkins an annual minimum royalty of up to \$30 and to make milestone payments to Johns Hopkins upon the achievement of specified technical and commercial milestones. If all such milestones were achieved, the total milestone payments owed to Johns Hopkins would equal \$700 in the aggregate. During the year ended December 31, 2015, the Company expensed \$50 upon the achievement of two of these milestones. The Company has not achieved any other milestones and, therefore, no additional liabilities for such milestone payments have been recorded in the Company’s financial statements.

The Company must also pay Johns Hopkins single digit percentage royalties on aggregate worldwide net sales of licensed products (but not galeterone), including sales by sublicensees, on a licensed product-by-licensed product and country-by-country basis until the later of the expiration of the last-to-expire applicable licensed patent or ten years after first commercial sale of the applicable licensed product, in each case in the applicable country. These royalty obligations are subject to specified reductions in the event that additional licenses from third parties are required. The Company must also pay Johns Hopkins 20% of all non-royalty sublicense income received from sublicensees and reimburse Johns Hopkins for patent costs. As of September 30, 2016, the Company has not yet developed a commercial product using the licensed technologies.

Companion Diagnostic Development Agreement

In March 2015, the Company entered into a project work plan with Qiagen Manchester Limited (“Qiagen”) under a Master Collaboration Agreement, dated January 12, 2015, between the Company and Qiagen (together with the project work plan, the “CDx Agreement”). Pursuant to the CDx Agreement, Qiagen has agreed to develop and commercialize a companion diagnostic test for use with galeterone to identify mCRPC patients with the AR-V7 splice variant. Qiagen has also developed under the CDx Agreement a clinical trial assay that was used in the Company’s pivotal Phase 3 clinical trial of galeterone in order to identify mCRPC patients whose tumor cells express AR-V7, and that may be used in future clinical trials of galeterone.

Tokai Pharmaceuticals, Inc.

Notes to Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

Subject to the terms of the CDx Agreement, the Company paid Qiagen a fee for the exclusive right to have the circulating tumor cell enrichment technology used in the development of the companion diagnostic test, which was recognized as research and development expense during the nine months ended September 30, 2015. The Company also paid Qiagen fees for the development of the AR-V7 clinical trial assay. On October 28, 2016, the Company and Qiagen entered into an agreement terminating the project work plan effective September 27, 2016. The Company is responsible for making a final payment of \$1,099 to Qiagen at which time there will be no future financial obligations by the Company or Qiagen under the project work plan. The Company recorded research and development expense of \$1,099 in the three and nine months ended September 30, 2016 related to this final payment to Qiagen, which amount is included in accrued expenses at September 30, 2016.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers, which provide, among other things, that the Company will indemnify such directors and executive officers to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred material costs as a result of the indemnification agreements described above. In addition, the Company maintains directors and officers insurance coverage. The Company is unable to predict if any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows and has not accrued any material liabilities related to such possible obligations in its financial statements as of September 30, 2016.

Legal Proceedings

On August 1, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the U.S. District Court for the Southern District of New York against the Company, Jodie P. Morrison, and Lee H. Kalowski, entitled *Doshi v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:16-cv-06106 (“*Doshi* Action”). The plaintiff seeks to represent a class of purchasers of Company securities between June 24, 2015, and July 25, 2016, and alleges that, in violation of the Securities Exchange Act of 1934 (“Exchange Act”) and Rule 10b-5 promulgated thereunder, defendants made false and misleading statements and omissions about the Company’s clinical trials for its drug candidate, galeterone. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys’ fees. On October 3, 2016, the case was transferred to the U.S. District Court for the District of Massachusetts.

On August 19, 2016, a purported stockholder of the Company filed a putative class action lawsuit in the Superior Court of the State of California, County of San Francisco, against the Company, Jodie P. Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of the Company’s initial public offering (“IPO”), entitled *Jackie888, Inc. v. Tokai Pharmaceuticals, Inc., et al.*, No. CGC-16-553796. The lawsuit alleges that, in violation of the Securities Act of 1933 (“Securities Act”), the Company’s registration statement for its IPO made false and misleading statements and omissions about the Company’s clinical trials for galeterone. The plaintiff seeks to represent a class of purchasers of Company common stock in and/or traceable to the Company’s IPO. The lawsuit seeks, among other things,

Tokai Pharmaceuticals, Inc.

Notes to Financial Statements

**(Amounts in thousands, except share and per share data)
(Unaudited)**

unspecified compensatory damages, interest, costs, and attorneys' fees. On October 19, 2016, the defendants moved to dismiss or stay the action on grounds of *forum non conveniens*, and certain individual defendants moved to quash the plaintiff's summons for lack of personal jurisdiction.

On September 29, 2016, two purported stockholders of the Company filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts against the Company, Jodie Pope Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of the Company's IPO, entitled *Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:16-cv-11963 ("*Garbowski Action*"). The lawsuit alleges that the defendants and the Company's registration statement for its IPO made false and misleading statements and omissions about the Company's clinical trials for galeterone, in violation of the Securities Act, the Exchange Act, and Rule 10b-5. The plaintiffs seek to represent a class of purchasers of Company common stock in or traceable to the Company's IPO as well as a class of purchasers of Company common stock between September 17, 2014, and July 25, 2016. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. The plaintiff in the *Doshi Action* has filed a motion to consolidate the *Doshi* and *Garbowski* Actions for all purposes.

The Company believes it has valid defenses, and intends to engage in a vigorous defense of the litigation. However, the Company is unable to predict the ultimate outcome of these actions, and, therefore cannot estimate possible losses or ranges of losses, if any, or the materiality thereof. An unexpected unfavorable resolution of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

7. 401(k) Plan

The Company has a 401(k) plan available for participating employees who meet certain eligibility requirements. Eligible employees may defer a portion of their salary as defined by the plan. Company contributions to the plan may be made at the discretion of the Board of Directors. Since January 1, 2016, the Company has made matching contributions for the plan year ending December 31, 2016 at a rate of 100% of each employee's contribution up to a maximum matching contribution of 3% of the employee's eligible plan compensation and at a rate of 50% of each employee's contribution in excess of 3% up to a maximum of 5% of the employee's eligible plan compensation.

For the nine months ended September 30, 2016, the Company made matching contributions of \$119 for the plan year ending December 31, 2016.

8. Related Party Transaction

In September 21, 2016, the Company entered into a consulting agreement with Apple Tree Life Sciences, Inc. ("Apple Tree") under which Apple Tree agreed to provide consulting, advisory and related services to and for the Company from time to time. There is no fee for these services except for reimbursement of out of pocket expenses. Affiliates of Apple Tree beneficially own approximately 35% of the Company, and Dr. Seth Harrison, a member of the Company's board of directors, is a principal of Apple Tree.

INDEX TO OTIC CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
<i>Audited Consolidated Financial Statements for the Years Ended December 31, 2015 and 2014</i>	
Independent Auditors' Report to the Shareholders of Otic Pharma Ltd.	F-40
Consolidated Balance Sheets	F-42
Consolidated Statements of Operations	F-43
Consolidated Statements of Changes in Shareholders' Equity	F-44
Consolidated Statements of Cash Flows	F-45
Notes to the Consolidated Financial Statements	F-46
 <i>Unaudited Consolidated Financial Statements for the Nine Months Ended September 30, 2016 and 2015</i>	
Consolidated Balance Sheets	F-59
Consolidated Statements of Operations	F-60
Consolidated Statements of Cash Flows	F-61
Notes to the Consolidated Financial Statements	F-62



**INDEPENDENT AUDITORS' REPORT TO THE SHAREHOLDERS OF
OTIC PHARMA LTD.**

We have audited the consolidated financial statements of Otic Pharma Ltd. (the "Company") and its subsidiary which comprise the balance sheets as of December 31, 2015 and 2014, and the related Statements of Operations, Changes in Shareholders Equity and Cash Flows for the year and period then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Tel Aviv - Main Office

1 Azrieli Center Tel Aviv, 6701101 P.O.B. 16593
Tel Aviv, 6116402 □ Tel: +972 (3) 608 5555 □ Fax: +972 (3) 609 4022 □ info@deloitte.co.il

Jerusalem
3 Kiryat Ha'Mada
Har Hotzvim Tower
Jerusalem, 9777603
P.O.B. 45396
Jerusalem, 9145101

Tel: +972 (2) 501 8888
Fax: +972 (2) 537 4173
info-jer@deloitte.co.il

Haifa
5 Ma'aleh Hashichrur
P.O.B. 5648
Haifa, 3105502

Tel: +972 (4) 860 7333
Fax: +972 (4) 867 2528
info-haifa@deloitte.co.il

Beer Sheva
12 Alumot
Omer Industrial Park
P.O.B. 1369
Omer, 8496500

Tel: +972 (8) 690 9500
Fax: +972 (8) 690 9600
info-beersheva@deloitte.co.il

Eilat
The City Center
P.O.B. 583
Eilat, 8810402

Tel: +972 (8) 637 5676
Fax: +972 (8) 637 1628
info-eilat@deloitte.co.il

Deloitte
3 Azrieli Center
Tel Aviv, 6701101

Tel: +972 (3) 607 0500
Fax: +972 (3) 607 0501
info@deloitte.co.il

Deloitte Analytics
7 Hasivim
P.O.B. 7796
Petah Tikva, 4959368

Tel: +972 (77) 8322221
Fax: +972 (3) 9190372
info@deloitte.co.il

Seker - Deloitte
7 Giborey Israel St.
P.O.B. 8458
Netanya, 4250407

Tel: +972 (9) 892 2444
Fax: +972 (9) 892 2440
info@deloitte.co.il

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited, a UK private company limited by guarantee, and its network of member firms, each of which is a legally separate and independent entity. Please see www.deloitte.com/about for a detailed description of the legal structure of Deloitte Touche Tohmatsu Limited and its member firms.



Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for the year and period then ended in accordance with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. To date the Company has not generated revenues from its activities and has incurred substantial operating losses. The resulting operating losses raise substantial doubts about its ability to continue as a going concern. Management's plans concerning these matters are described in Note 1 to the financial statements. The financial statements do not include any adjustments that result from the outcome of these uncertainties.

/s/ **Brightman, Almagor Zohar & Co.**

Brightman, Almagor Zohar & Co.
Certified Public Accountants
Member of Deloitte Touche Tohmatsu Limited

January 16, 2017

Tel Aviv - Main Office

1 Azrieli Center Tel Aviv, 6701101 P.O.B. 16593
Tel Aviv, 6116402 □ Tel: +972 (3) 608 5555 □ Fax: +972 (3) 609 4022 □ info@deloitte.co.il

Jerusalem
3 Kiryat Ha'Mada
Har Hotzvim Tower
Jerusalem, 9777603
P.O.B. 45396
Jerusalem, 9145101

Tel: +972 (2) 501 8888
Fax: +972 (2) 537 4173
info-jer@deloitte.co.il

Haifa
5 Ma'aleh Hashichrur
P.O.B. 5648
Haifa, 3105502

Tel: +972 (4) 860 7333
Fax: +972 (4) 867 2528
info-haifa@deloitte.co.il

Beer Sheva
12 Alumot
Omer Industrial Park
P.O.B. 1369
Omer, 8496500

Tel: +972 (8) 690 9500
Fax: +972 (8) 690 9600
info-beersheva@deloitte.co.il

Eilat
The City Center
P.O.B. 583
Eilat, 8810402

Tel: +972 (8) 637 5676
Fax: +972 (8) 637 1628
info-eilat@deloitte.co.il

Deloitte
3 Azrieli Center
Tel Aviv, 6701101

Tel: +972 (3) 607 0500
Fax: +972 (3) 607 0501
info@deloitte.co.il

Deloitte Analytics
7 Hasivim
P.O.B. 7796
Petah Tikva, 4959368

Tel: +972 (77) 8322221
Fax: +972 (3) 9190372
info@deloitte.co.il

Seker - Deloitte
7 Giborey Israel St.
P.O.B. 8458
Netanya, 4250407

Tel: +972 (9) 892 2444
Fax: +972 (9) 892 2440
info@deloitte.co.il

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited, a UK private company limited by guarantee, and its network of member firms, each of which is a legally separate and independent entity. Please see www.deloitte.com/about for a detailed description of the legal structure of Deloitte Touche Tohmatsu Limited and its member firms.

OTIC PHARMA LTD.
CONSOLIDATED BALANCE SHEETS
U.S. Dollars in thousands except share data

	Note	December 31	
		2015	2014
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents		\$ 3,095	\$ 1,565
Restricted cash		14	14
Other current receivables	3	100	32
Total current assets		<u>3,209</u>	<u>1,611</u>
NON-CURRENT ASSETS			
Property and equipment, net	4	76	26
Other non-current assets		13	—
Total non-current assets		<u>89</u>	<u>26</u>
		<u>\$ 3,298</u>	<u>\$ 1,637</u>
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES			
Trade accounts payable		\$ 354	\$ 42
Other current liabilities	6	162	92
Total current liabilities		<u>516</u>	<u>134</u>
Total liabilities		<u>516</u>	<u>134</u>
COMMITMENTS AND CONTINGENCIES			
	7		
SHAREHOLDERS' EQUITY			
	8		
Ordinary shares, NIS 0.01 par value;			
Authorized 8,600,118 shares as of December 31, 2015 and 6,000,010 shares as of December 31, 2014;			
Issued and outstanding: 700,705 shares as of December 31, 2015 and 554,681 shares as of December 31, 2014.		1	1
Preferred shares, NIS 0.01 par value;			
Authorized 5,958,682 shares as of December 31, 2015 and 5,018,590 shares as of December 31, 2014;			
Issued and outstanding: 4,074,354 shares as of December 31, 2015 and 3,134,262 shares as of December 31, 2014.		11	9
Additional paid-in-capital		11,214	5,723
Receipts on Account of Preferred A Shares		291	291
Accumulated deficit		<u>(8,735)</u>	<u>(4,521)</u>
Total shareholders' equity		<u>2,782</u>	<u>1,503</u>
		<u>\$ 3,298</u>	<u>\$ 1,637</u>

January 16, 2017

**Date of approval of the
financial statements****/s/ Christine G. Ocampo**
Christine G. Ocampo, CFO**/s/ Gregory J. Flesher**
Gregory J. Flesher, CEO

OTIC PHARMA LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
U.S. Dollars in thousands except share and per share data

		For the year ended	
		December 31,	
	Note	2015	2014
Research and development expenses, net	9	\$ 2,774	\$ 946
General and administrative expenses	10	1,415	208
Operating loss		(4,189)	(1,154)
Other income (expense), net		25	6
Loss for the year		\$ (4,214)	\$ (1,160)
Net loss used in the calculation of basic and diluted net loss per share	12	\$ (687)	\$ (270)
Basic and diluted loss per share	12	\$ (1.13)	\$ (0.49)
Weighted average ordinary shares outstanding, basic and diluted		605,520	554,681

OTIC PHARMA LTD.
STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
 U.S. Dollars in thousands except share data

	Ordinary Shares		Preferred Shares		Additional Paid in Capital	Receipts on account of shares	Accumulated Deficit	Total
	Shares	Amounts	Shares	Amounts				
Balance as of December 31, 2013	554,681	\$ 1	2,368,826	\$ 7	\$ 4,144	\$ 291	\$ (3,361)	\$ 1,082
Issuance of shares and warrants	—	—	765,436	2	1,498	—	—	1,500
Share-based payment	—	—	—	—	81	—	—	81
Loss for the year	—	—	—	—	—	—	(1,160)	(1,160)
Balance as of December 31, 2014	554,681	1	3,134,262	9	5,723	291	(4,521)	1,503
Issuance of shares and warrants	146,024(**)	—	940,092	2(*)	5,381	—	—	5,383
Share-based payment	—	—	—	—	110	—	—	110
Loss for the year	—	—	—	—	—	—	(4,214)	(4,214)
Balance as of December 31, 2015	<u>700,705</u>	<u>\$ 1</u>	<u>4,074,354</u>	<u>\$ 11</u>	<u>\$ 11,214</u>	<u>\$ 291</u>	<u>(8,735)</u>	<u>\$ 2,782</u>

(*) Net of \$51 of issuance expenses.

(**) Less than \$1.

OTIC PHARMA LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. Dollars in thousands

	For the year ended December 31,	
	<u>2015</u>	<u>2014</u>
CASH FLOWS — OPERATING ACTIVITIES		
Loss for the year	\$ (4,214)	\$ (1,160)
Adjustments to reconcile loss from operations to net cash used for operating activities:		
Depreciation	12	9
Share-based compensation to employees	110	81
License fees paid in shares	93	—
Changes in operating assets and liabilities:		
Decrease (increase) in other receivables	(81)	149
Increase in trade accounts payable	312	19
Decrease (increase) in other current liabilities	70	(10)
Net cash used for operating activities	<u>(3,698)</u>	<u>(912)</u>
CASH FLOWS—INVESTING ACTIVITIES		
Purchase of property and equipment	(62)	—
Net cash provided by investing activities	<u>(62)</u>	<u>—</u>
CASH FLOWS—FINANCING ACTIVITIES		
Issuance of shares and warrants	5,290	1,500
Net cash provided by financing activities	<u>5,290</u>	<u>1,500</u>
Increase in cash and cash equivalents	1,530	588
Cash and cash equivalents—beginning of year	<u>1,565</u>	<u>977</u>
Cash and cash equivalents—end of year	<u>\$ 3,095</u>	<u>\$ 1,565</u>

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 1—GENERAL

Otic Pharma, Ltd. (the “Company” or “Otic”) is a clinical-stage, specialty pharmaceutical company focused on the acquisition and development of products for disorders of the ear, nose, and throat (ENT). Otic was founded in Israel in 2008. In 2015, Otic established U.S. operations, Otic Pharma, Inc., (the “Subsidiary”) and moved its corporate headquarters to Southern California. Otic has two novel technologies that are initially being developed for conditions of the ear.

OP-01 is a foam-based technology. It was developed by Otic with the intent to be used as a delivery vehicle for drugs which are to be placed into the ears, as well as the nasal and sinus cavities. OP-01 is currently being developed as an improved treatment option for acute otitis externa (AOE or “swimmers ear”), a common medical condition of the outer ear canal that globally affects tens of millions of adults and children every year. Otic has completed four clinical trials, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP-01 that performed similarly to standard of care. Otic is now planning to further modify the foam formulation to create a clinically differentiated, best-in-class product for AOE that is an improvement to the standard of care.

OP-02 is a surfactant-based technology. It was originally developed by Otodyne, Inc. and subsequently licensed to Otic in November 2015. OP-02 is currently being developed as a potential first-in-class treatment option for patients with otitis media (OM) and Eustachian tube dysfunction (ETD). OM and ETD are common medical conditions of the middle ear that globally affects more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice and it is the most frequent reason children are prescribed antibiotics and undergo surgery. OP-02 is a daily nasal spray, designed to improve and maintain the Eustachian tube’s ability to drain and ventilate the middle ear. In 2017, Otic is planning to initiate phase 1 clinical studies to explore the safety and tolerability of OP-02, as well as explore how OP-02 affects the Eustachian tube (pharmacodynamics). Studies will evaluate single and repeated intranasal doses of OP-02. Upon completion of these studies, Otic will begin phase 2 with a focus on prevention of acute, recurrent, and chronic OM in children.

GOING CONCERN:

To date the Company has not generated revenues from its activities and has incurred substantial operating losses. Management expects the Company to continue to generate substantial operating losses and to continue to fund its operations primarily through utilization of its current financial resources and through additional raises of capital.

Such conditions raise substantial doubts about the Company’s ability to continue as a going concern. Management’s plan includes raising funds from outside potential investors. However, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. These financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

NOTE 2—SIGNIFICANT ACCOUNTING POLICIES

A. Basis of Presentation:

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 2—SIGNIFICANT ACCOUNTING POLICIES (Cont.)

B. Use of estimates in the preparation of financial statements:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgment and assumptions can affect reported amounts and disclosures made. Actual results could differ from those estimates.

C. Financial Statements in U.S. Dollars:

The functional currency of the Company is the U.S dollar ("USD") since the U.S. dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future.

Transactions and balances denominated in USD are presented at their original amounts. Transactions and balances denominated in foreign currencies have been re-measured to USD in accordance with the provisions of ASC 830-10, "Foreign Currency Translation".

All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of operations as financial income or expenses, as appropriate.

D. Cash and cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with maturities of three months or less as of the date acquired.

E. Restricted cash:

Restricted cash is primarily invested in highly liquid deposits with original maturities of less than three months, which are used as securities for rental payments.

F. Property and equipment:

Property and equipment are presented at cost less accumulated depreciation and amortization. Depreciation and amortization are calculated based on the straight-line method over the estimated useful lives of the related assets or terms of the related leases, as follows:

	%
Computers	33
Furniture and office equipment	7-20
Lab equipment	15
Leasehold improvement	over the related period

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 2—SIGNIFICANT ACCOUNTING POLICIES (Cont.)

G. Share-based compensation:

The Company applies ASC 718-10, “Share-Based Payment,” which requires the measurement and recognition of compensation expenses for all share-based payment awards, including employee stock options under the Company’s stock plans, based on estimated fair values. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company’s statement of operations.

The Company estimates the fair value of stock options granted as equity awards using the Black-Scholes options pricing model. The option-pricing model requires a number of assumptions, of which the most significant are share price, expected volatility and the expected option term (the time from the grant date until the options are exercised or expire). Expected volatility is estimated based on volatility of similar companies in the pharmaceutical sector. The Company has historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from governmental zero-coupon bonds with an equivalent term. The expected option term is calculated using the “simplified” method.

H. Basic and diluted net loss per share:

Basic loss per share is computed by dividing the net loss, as adjusted to include preferred shares dividend participation rights as well as interest accumulated on preferred shares, by the weighted average number of ordinary shares outstanding during the year. Shares and preferred shares contingently issuable for little or no cash are included in basic loss per share on an as issued basis.

Diluted loss per share is computed by dividing the net loss, as adjusted to include preferred shares dividend participation rights as well as interest accumulated on preferred shares, of preferred shares outstanding during the year as well as of preferred shares that would have been outstanding if all potentially dilutive preferred shares had been issued, by the weighted average number of ordinary shares outstanding during the year, plus the number of ordinary shares that would have been outstanding if all potentially dilutive ordinary shares had been issued, using the treasury stock method, in accordance with ASC 260-10 “Earnings per Share”.

Potentially dilutive shares were excluded from the calculation of diluted loss per share for all periods presented due to their anti-dilutive effect. The number of such anti-dilutive shares excluded from the calculation is 2,195,101 and 1,316,418 for the year ended December 31, 2015 and 2014, respectively.

I. Research and development expenses, net:

Research and development expenses, are charged to the statement of operations as incurred. Grants for funding of approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred and applied as a deduction from the research and development expenses.

J. Fair value of financial instruments:

The financial instruments of the company consist mainly of cash and cash equivalents, other receivables, restricted cash, trade accounts payable and other current liabilities. In view of their nature,

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 2—SIGNIFICANT ACCOUNTING POLICIES (Cont.)

J. Fair value of financial instruments (Cont.):

the fair value of the financial instruments included in working capital of the Company is usually identical or substantially similar to their carrying amounts.

K. Income taxes:

- (1) The Company uses the liability method to determine its income tax expense as required under the Statement of ASC 740-10. ASC 740-10 requires the establishment of a deferred tax asset or liability for the recognition of future deductible or taxable temporary differences and operating loss carry forwards. Valuation allowances are established when necessary; to reduce deferred tax assets, if it is more likely than not that all or a portion of it will not be realized.
- (2) The Company does not create deferred tax assets for accumulated tax losses and timing differences, since there is no certainty for taxable income in the foreseeable future.

L. Recent Accounting Standards

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued a new standard to achieve a consistent application of revenue recognition within the U.S., resulting in a single revenue model to be applied by reporting companies under U.S. generally accepted accounting principles. Under the new model, recognition of revenue occurs when a customer obtains control of the promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the new standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The new standard is effective beginning in the first quarter of 2018; early adoption is prohibited. The new standard is required to be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. As the Company has not incurred revenues to date, it is unable to determine the expected impact the new standard will have on its consolidated financial statements.

In January 2016, the FASB issued an amended standard requiring changes to recognition and measurement of certain financial assets and liabilities. The standard primarily affects equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. This standard is effective beginning in the first quarter of 2018. Certain provisions allow for early adoption. The Company does not expect that the adoption of this standard will have a significant impact on the financial position or results of operations.

In February 2016, the FASB issued a new lease accounting standard requiring the recognition of lease assets and liabilities on the balance sheet. This standard is effective beginning in the first quarter of 2019; early adoption is permitted. The Company has not yet determined the impact of the new standard on its consolidated financial statements.

In March 2016, the FASB issued an accounting standard update aimed at simplifying the accounting for share-based payment transactions. Included in the update are modifications to the accounting for income taxes upon vesting or settlements of awards, employer tax withholding on share-based

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
 U.S. Dollars in thousands except share and per share data

NOTE 2—SIGNIFICANT ACCOUNTING POLICIES (Cont.)

L. Recent Accounting Standards (Cont.)

compensation, forfeitures, and financial statement presentation of excess tax benefits. This standard is effective beginning in the first quarter of 2017; early adoption is permitted. The Company does not expect that the adoption of this standard will have a significant impact on the financial position or results of operations.

In June 2016, the FASB issued a new standard requiring measurement and recognition of expected credit losses on certain types of financial instruments. The new standard also modifies the impairment model for available-for-sale debt securities and provides for a simplified accounting model for purchased financial assets with credit deterioration since their origination. This standard is effective beginning in the first quarter of 2020; early adoption is permitted starting from the first quarter of 2019. The Company does not expect that the adoption of this standard will have a significant impact on the financial position or results of operations.

NOTE 3—OTHER CURRENT RECEIVABLES

	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
Prepaid expenses	\$ 70	\$ 12
Government institutions	25	10
Income receivable- Office of Chief Scientist (“OCS”)	5	10
	<u>\$ 100</u>	<u>\$ 32</u>

NOTE 4—PROPERTY AND EQUIPMENT, NET

	<u>Computer and software</u>	<u>Furniture and office equipment</u>	<u>Lab equipment</u>	<u>Leasehold improvement</u>	<u>Total</u>
Cost:					
As of January 1, 2015	\$ 15	\$ 7	\$ 35	\$ —	\$ 57
Additions	6	54	—	2	62
As of December 31, 2015	<u>21</u>	<u>61</u>	<u>35</u>	<u>2</u>	<u>119</u>
Accumulated depreciation:					
As of January 1, 2015	12	2	17	—	31
Additions	3	4	5	—	12
As of December 31, 2015	<u>15</u>	<u>6</u>	<u>22</u>	<u>—</u>	<u>43</u>
Net book value:					
As of December 31, 2015	<u>\$ 6</u>	<u>\$ 55</u>	<u>\$ 13</u>	<u>\$ 2</u>	<u>\$ 76</u>
As of December 31, 2014	<u>\$ 3</u>	<u>\$ 5</u>	<u>\$ 18</u>	<u>\$ —</u>	<u>\$ 26</u>

NOTE 5—EMPLOYEE RIGHTS UPON RETIREMENT

Israeli labor law generally requires payment of severance pay upon dismissal of an employee or upon termination of employment in certain other circumstances.

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 5—EMPLOYEE RIGHTS UPON RETIREMENT (Cont.)

Pursuant to section 14 of the Severance Compensation Act, 1963, the Company's employees covered under this section are entitled to monthly deposits, at a rate of 8.33% of their monthly salary, made in their name with insurance companies. Payments in accordance with section 14 relieve the Company from any future severance payments in respect of those employees.

The Company is not statutorily required by U.S. law to pay severance upon termination of employment in respect of its U.S. employees.

NOTE 6—OTHER CURRENT LIABILITIES

	December 31,	
	2015	2014
Employees and related institutions	\$ 149	\$ 66
Accrued expenses and others	13	26
	<u>\$ 162</u>	<u>\$ 92</u>

NOTE 7—COMMITMENTS AND CONTINGENCIES

A. OCS Grants:

<u>Grant</u>	U.S. Dollars in thousands	<u>Conditions</u>
OCS	\$ 537	
OCS grants receivable	5	
	<u>\$ 542</u>	

As of December 31, 2015, the Company received loans in the amount of approximately \$537 thousands from the OCS designated for the Company's investments in research and development. The said loans are linked to the Dollar and bear annual interest of LIBOR. The loans are to be repaid out of royalties from sales of the products developed by the Company from the investments in research and development.

B. Lease Agreement:

In September 2015, the Subsidiary entered into a Lease Agreement (the "Lease Agreement") for approximately 5,113 square feet of office space located in Irvine, California. The lease has a 36-month term beginning September 1, 2015. Monthly rent begins at \$13 per month, with scheduled annual rent increases of 4% thereafter.

C. License Agreement:

In November 2015, the Subsidiary entered into an Exclusive License Agreement (the "License Agreement") with Scientific Development and Research Inc. and Otodyne Inc. (the "Licensors"). According to which the Licensors shall provide the License Technology, as defined in the License

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 7—COMMITMENTS AND CONTINGENCIES (Cont.)

Agreement, to the Subsidiary. In return to the License Agreement, the Subsidiary will pay to the Licensors a license fee in a total amount of \$600, and the Company will issue to the Licensors 88,024 Ordinary Shares NIS 0.01 par value each (see note 8 D). In addition, the Subsidiary will pay additional amount of \$100 as a Technology Transfer Fee as defined in the License Agreement, and future milestones and royalty payments, as defined and detailed in the License Agreement.

As of Dec 31 2015, the Company paid to the Licensors \$650 in cash as well as \$93 in ordinary shares. The related expense was included in the statement of operations as research and development expense. The share-based expense was valued based on an estimated ordinary share price of \$1.06.

NOTE 8—SHARE CAPITAL

A. Composition:

	December 31, 2015		December 31, 2014	
	Authorized	Issued	Authorized	Issued
	Number of shares		Number of shares	
Ordinary Shares of NIS 0.01 nominal value	8,600,118	700,705	6,000,010	554,681
Preferred A Shares NIS 0.01 nominal value	691,000	493,551	691,000	493,551
Preferred B Shares NIS 0.01 nominal value	4,327,590	2,640,711	4,327,590	2,640,711
Preferred C Shares NIS 0.01 nominal value	940,092	940,092	—	—
Receipts on account of Preferred A Shares	—	—	—	—
	<u>14,558,800</u>	<u>4,775,059</u>	<u>11,018,600</u>	<u>3,688,943</u>

Ordinary Shares:

Ordinary Shares confer upon the holders thereof the right to receive notice of, participate in, and vote at general meetings of the Company. Holders also have the right to receive cash and stock dividends, if declared or upon dissolution, subject to the preferential rights of the holders of the series of Preferred Shares.

Preferred Shares:

Preferred Shares are convertible into ordinary shares at the option of their holders, and confer upon their holders all rights accruing to holders of Ordinary Shares in the Company on an as converted basis. In addition, holders of Preferred Shares are entitled to preference upon a liquidation event and upon distribution of dividends, plus 8% annual interest calculated on the preferred share original issue price, as further detailed in the Company's Articles of Association.

Interest accumulated on preferred shares as of December 31 2015 and 2014 was \$1,800 and \$1,150, respectively.

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 8—SHARE CAPITAL (Cont.)

Receipts on account of Preferred A Shares:

On June 20, 2010, Incentive II Management Ltd. (“Incentive”) provided Otic Pharma with a loan (the “Incentive Loan”) under a Convertible Loan Agreement (the “Loan Agreement”) between Otic Pharma and Incentive. As part of the closing of the Series B Preferred Shares Purchase Agreement in February 2012, Incentive, Otic Pharma and the Series B Investors agreed that the Incentive Loan provided by Incentive shall be convertible by Incentive into 196,714 Preferred A Shares (the “Incentive A Shares”), which conversion shall occur upon request by Incentive (the “Formal Conversion”). Until the Formal Conversion, the Incentive A Shares that are issuable to Incentive are deemed issued and outstanding and held by Incentive for all intents and purposes and the loan provided shall be deemed, for all intents and purposes, as repaid in full pursuant to its terms. As the underlying shares have not been issued as of December 31, 2015, the funds received in their regard are presented as receipts on account of shares on the Company’s shareholders equity statement.

- B.** During 2012-2013, the Company entered into the Share Purchase Agreement and into several amendments thereto (the “Series B SPA”) with OrbiMed and other investors (collectively, “the Series B Investors”). In accordance with the Series B SPA, the Series B Investors invested during 2012-2014 a total amount of \$4,730 for 2,413,676 Series B Preferred Shares and 1,577,818 warrants.

In addition, pursuant the Series B SPA, the convertible loans provided to the Company by the lenders in the aggregate amount of \$330 were converted into 227,035 Series B Preferred Shares and 109,056 warrants to purchase Series B Preferred Shares.

- C.** In May, October and November 2015, the Company entered into a Share Purchase Agreement and into several amendments thereto (the “Series C SPA”) with existing and new investors (collectively, the “Series C Investors”). In accordance to the Series C SPA, the Investors invested \$5,340 for 940,092 Series C Preferred Shares. In addition, the Series C Investors received 286,435 Warrants to purchase 286,435 Ordinary Shares of the Company at an exercise price equal to the underlying shares par value.

- D.** In November 2015, the Company issued 88,024 Ordinary Shares, as part of the License Agreement. See Note 7 (C).

E. Share-based payment:

- (1) In May 2015, the Company entered into a Restricted Share Award Agreement with a Director (the “Director”), according to which the Company shall issue to the Director 58,000 restricted Ordinary Shares (the “Restricted Share”) for a total consideration of \$61 thousands. The Company has the right and option to purchase from the Director some or all of the Restricted Shares issued, as defined and detailed in the Restricted Share Award Agreement (the “Purchase Option”). The shares will be released from the Company’s Purchase Option during a period of 4 years.
- (2) During 2014, the Company’s Board of Directors approved a placement of 14,500 options to Company’s employee. The Options were granted in accordance with the “capital gains route” provided under Sections 102 of the Income Tax Ordinance.

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 8—SHARE CAPITAL (Cont.)

The options shall vest as follows: 25% of the options shall vest on the first anniversary of the vesting Commencement date. The remaining options shall vest in equal monthly installments for a period of 36 Months.

During 2015, the employee's employment ended and accordingly, all the 14,500 options expired.

- (3) During 2015, the Company's Board of Directors approved an additional placement of 1,021,864 options to the Company's employees, director and the Subsidiary employees. The Options were granted in accordance with the "capital gains route" provided under Sections 102 of the Income Tax Ordinance, and section 409A according to the IRS Code.

180,825 options granted shall vest in accordance with several milestones and/or achievements, and another 899,039 options granted shall vest as follows: 25% of the options shall be vested on the first anniversary of the vesting commencement date, and 75% of the Options shall be vested on a quarterly basis during the next 3 years.

- (4) The parameters used for purposes of the model were as follows:

	Year ended December 31,	
	2015	2014
Exercise price (USD)	\$1.06	\$0.58
Fair value per share (USD)	\$1.06	\$1.06
Anticipated volatility (*) (Percentage)	93	93
Term of the option (in years)	5.5-7	5.5-7
Risk-free interest rate (Percentage) (**)	0.95	0.98

(*) Expected volatility was determined based on historical volatility of stock prices of similar publicly-traded companies, who operate in the same field and have a similar business risk level.

(**) Risk-free interest rate was derived from the interest curve of U.S. Government Treasury Bonds for a period corresponding to the term of the options when granted.

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
 U.S. Dollars in thousands except share and per share data

NOTE 8—SHARE CAPITAL (Cont.)

(5) A summary of activity of options granted to purchase the Company's Shares under the Company's share option plan is as follows:

	Year ended December 31,			
	2015		2014	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	179,025	\$ 0.39	164,525	\$ 0.37
Granted	1,021,864	\$ 1.06	14,500	\$ 0.58
Expired	(14,500)	\$ 0.58	—	\$ —
Outstanding at end of year	<u>1,186,389</u>	\$ 0.97	<u>179,025</u>	\$ 0.39

The total stock-based compensation expense for the year ended December 31, 2015 resulting from options granted to employees in a total amount of \$98, is included in the Company's statement of operations as general and administrative expenses.

(6) Options issued to non-employees:

The Company's outstanding options to non-employees as of December 31, 2015, are as follows:

	Options to Common stock	Weighted average exercise price	Options exercisable
July 2012	47,724	\$ 0.36	46,151
December 2015	125,000	\$ 1.06	10,000
	<u>172,724</u>	\$ 0.70	<u>56,151</u>

The total stock-based compensation expense for the year ended December 31, 2015 resulting from options granted to non—employees in a total amount of \$4, included in the Company's statement of operations in the general and administrative expenses.

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 9—RESEARCH AND DEVELOPMENT EXPENSES, NET

	<u>For the year ended</u>	
	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
Subcontractors and consultants	\$ 1,138	\$ 386
License fee (*)	743	—
Salaries and related expenses	739	468
Vehicle maintenance	62	58
Patents	59	63
Travel abroad	57	14
Share-based payments	34	81
Depreciation	9	9
Materials	1	9
	<u>2,842</u>	<u>1,088</u>
Less—Grants from OCS	(68)	(142)
	<u>\$ 2,774</u>	<u>\$ 946</u>

(*) See note 7 (C)

NOTE 10—GENERAL AND ADMINISTRATIVE EXPENSES

	<u>For the year ended</u>	
	<u>December 31,</u>	
	<u>2015</u>	<u>2014</u>
Professional services	\$ 699	\$ 139
Salaries and related expenses	377	11
Rent and office maintenance	171	58
Travel abroad	77	—
Share-based payments	76	—
Investor relations	12	—
Depreciation	3	—
	<u>\$ 1,415</u>	<u>\$ 208</u>

NOTE 11—TAXES ON INCOME

The Company is subject to income taxes under the Israeli and U.S. tax laws:

1. Corporate tax rates

The Company is subject to Israeli corporate tax rate of 26.5% in the years 2015 and 2014, 25% in the year 2016, 24% in 2017 and 23% from 2018.

The Company is subject to a blended U.S. tax rate (Federal as well as state corporate tax) of 35%.

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 11—TAXES ON INCOME (Cont.)

2. As of December 31, 2015, the Company generated net operating losses in Israel of approximately \$5,125, which may be carried forward and offset against taxable income in the future for an indefinite period.

As of December 31, 2015, the Company generated net operating losses in the U.S. of approximately \$919. Net operating losses in the United States are available through 2035. Utilization of U.S. net operating losses may be subject to substantial annual limitation due to the “change in ownership” provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

3. The Company is still in its development stage and has not yet generated revenues, therefore, it is more likely than not that sufficient taxable income will not be available for the tax losses to be utilized in the future. Therefore, a valuation allowance was recorded to reduce the deferred tax assets to its recoverable amounts.

	As of December 31	
	2015	2014
Net loss carry-forward	\$ 1,680	\$ 929
Other reserves	418	223
Total deferred tax assets	2,098	1,152
Valuation allowance	(2,098)	(1,152)
Net deferred tax assets	\$ —	\$ —

NOTE 12—BASIC LOSS PER SHARE

The loss and weighted average number of ordinary shares used in the calculation of basic loss per share are as follows:

	For the year ended	
	December 31,	
	2015	2014
Numerator:		
Net loss available to shareholders of the company	\$ (4,214)	\$ (1,160)
Interest accumulated on preferred shares and on preferred shares contingently issuable for little or no cash	(651)	(374)
Net loss attributable to shareholders of preferred shares and to shareholders of preferred shares contingently issuable for little or no cash	4,178	1,264
Net loss used in the calculation of basic loss per share	(687)	(270)
Denominator:		
Weighted average number of ordinary shares	605,520	554,681
Net loss per share	\$ (1.13)	\$ (0.49)

OTIC PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
U.S. Dollars in thousands except share and per share data

NOTE 13—TRANSACTIONS WITH RELATED PARTIES

Transactions with related parties:

	For the year ended December 31,	
	2015	2014
Consulting fees to related parties ⁽¹⁾	<u>\$ 44</u>	<u>\$ 50</u>

In the fiscal years ended December 31, 2015 and 2014, consulting fees were paid to a member of the Board.

NOTE 14—SUBSEQUENT EVENTS

- (1) In July 2016, the Company entered into a Convertible Loan Agreement (the “CLA”) with current Investors (the “Investors”). In accordance with the CLA, the Company will receive from the Investors, a Bridge Financing in an aggregate amount of \$2,930 (the “Bridge Financing Amount”) as defined in the CLA. As of the date of the approval of the financial statements, the Company received a total amount of \$2,930.
- (2) In September 2016, the Company consolidated the oversight and management of all research and development activities to the Subsidiary. The Group expects operations in the Israel office to conclude by November 30, 2016. Intellectual property will remain under the ownership of the Company.
- (3) On December 21, 2016, the Company entered into a Share Purchase Agreement to merge with Tokai in an all-stock transaction. On a pro forma basis, based upon the number of shares of Tokai common stock to be issued in accordance with the Share Purchase Agreement, Tokai equity holders will own approximately 40% of the combined company and Otic equity holders will own approximately 60% of the combined company. The transaction has been approved by the board of directors of both companies and by the shareholders of Otic. The transaction is expected to close in the first half of 2017, subject to the approval of the stockholders of Tokai and other customary closing conditions, as detailed in the Share Purchase Agreement.

In connection with the transaction, Otic will be deemed to be the accounting acquirer and therefore the transaction will be treated as a reverse acquisition because (i) Otic security holders are expected to own approximately 60% of the voting interests of the combined company immediately following the closing of the transaction; (ii) directors appointed by Otic will hold a majority of the board seats in the combined company; and (iii) Otic management will hold all key positions in the management of the combined company.

[Table of Contents](#)

Otic Pharma, Ltd.
Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,372	\$ 3,095
Restricted cash	14	14
Other current assets	71	100
Total current assets	2,457	3,209
Property and equipment, net	72	76
Other non-current assets	—	13
Total assets	\$ 2,529	\$ 3,298
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 68	\$ 354
Accrued expenses	230	162
Convertible debt	3,447	—
Total current liabilities	3,745	516
Total liabilities	3,745	516
Commitments and contingencies (Note 5)		
Shareholders' deficit:		
Ordinary Shares, NIS 0.01 par value, 740,215 and 700,705 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	1	1
Preferred Shares, NIS 0.01 par value, 4,074,354 shares issued and outstanding at September 30, 2016 and December 31, 2015	11	11
Additional paid-in capital	11,356	11,214
Receipts on account of Preferred A Shares	291	291
Accumulated deficit	(12,875)	(8,735)
Total shareholders' deficit	(1,216)	2,782
Total liabilities and shareholders' deficit	\$ 2,529	\$ 3,298

See notes to consolidated financial statements.

[Table of Contents](#)

Otic Pharma, Ltd.
Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Nine months ended September 30,	
	2016	2015
Revenue	\$ —	\$ —
Operating expenses:		
Research and development expenses, net	2,335	1,521
General and administrative expenses	1,326	566
Total operating expenses	3,661	2,087
Loss from operations	(3,661)	(2,087)
Other income (expense), net	(479)	17
Net loss	\$ (4,140)	\$ (2,070)
Net loss used in the calculation of basic and diluted net loss per share	\$ (718)	\$ (582)
Net loss per share, basic and diluted	\$ (1.01)	\$ (0.65)
Weighted average ordinary shares outstanding, basic and diluted	711,231	898,436

See notes to consolidated financial statements.

Otic Pharma, Ltd.
Consolidated Statements of Cash Flows
(in thousands, except share and per share data)
(unaudited)

	Nine months ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (4,140)	\$ (2,070)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	16	7
Share-based compensation expense	142	31
Fair value of debt in excess of proceeds	517	—
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Other current and non-current assets	42	(46)
Restricted cash	—	14
Increase (decrease) in:		
Accounts payable	(286)	301
Accrued expenses	68	39
Net cash used in operating activities	<u>(3,641)</u>	<u>(1,724)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(12)	(7)
Net cash used in investing activities	<u>(12)</u>	<u>(7)</u>
Cash flows from financing activities:		
Proceeds from convertible loan	2,930	—
Proceeds from issuance of Series C Preferred stock	—	1,903
Net cash provided by financing activities	<u>2,930</u>	<u>1,903</u>
Net increase (decrease) in cash and cash equivalents	(723)	172
Cash and cash equivalents at beginning of period	<u>3,095</u>	<u>1,565</u>
Cash and cash equivalents at end of period	<u><u>\$ 2,372</u></u>	<u><u>\$ 1,737</u></u>

See notes to consolidated financial statements.

Notes to the Consolidated Financial Statements (unaudited)

Note 1. Description of Business

Otic Pharma, Ltd. (the “Company” or “Otic”) is a clinical-stage, specialty pharmaceutical company focused on the acquisition and development of products for disorders of the ear, nose, and throat (ENT). Otic was founded in Israel in 2008. In 2015, Otic established U.S. operations, Otic Pharma, Inc., (the “Subsidiary”) and moved its corporate headquarters to Southern California. Otic has two novel technologies that are initially being developed for conditions of the ear.

OP-01 is a foam-based technology. It was developed by Otic with the intent to be used as a delivery vehicle for drugs which are to be placed into the ears, as well as the nasal and sinus cavities. OP-01 is currently being developed as an improved treatment option for acute otitis externa (AOE or “swimmers ear”), a common medical condition of the outer ear canal that globally affects tens of millions of adults and children every year. Otic has completed four clinical trials, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP-01 that performed similarly to standard of care. Otic is now planning to further modify the foam formulation to create a clinically differentiated, best-in-class product for AOE that is an improvement to the standard of care.

OP-02 is a surfactant-based technology. It was originally developed by Otodyne, Inc. and subsequently licensed to Otic in November 2015. OP-02 is currently being developed as a potential first-in-class treatment option for patients with otitis media (OM) and Eustachian tube dysfunction (ETD). OM and ETD are common medical conditions of the middle ear that globally affects more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice and it is the most frequent reason children are prescribed antibiotics and undergo surgery. OP-02 is a daily nasal spray, designed to improve and maintain the Eustachian tube’s ability to drain and ventilate the middle ear. In 2017, Otic is planning to initiate phase 1 clinical studies to explore the safety and tolerability of OP-02, as well as explore how OP-02 affects the Eustachian tube (pharmacodynamics). Studies will evaluate single and repeated intranasal doses of OP-02. Upon completion of these studies, Otic will begin phase 2 with a focus on prevention of acute, recurrent, and chronic OM in children.

Otic has no products approved for commercial sale. Otic has not generated any revenue and has incurred significant operating losses in each year since its inception in 2008. Substantially all of Otic’s operating losses resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations. Otic will need to expend substantial resources and expects to continue to generate operating losses for the foreseeable future as it continues to pursue its research and development programs for the treatment of AOE and OM. Otic is subject to a number of risks and uncertainties similar to those of other life science companies developing new products, including, among others, the risks related to the necessity to obtain adequate additional financing, to successfully develop product candidates, to obtain regulatory approval of product candidates, to comply with government regulations, to successfully commercialize its potential products, to the protection of proprietary technology and to the dependence on key individuals. Furthermore, due to the uncertainty of pharmaceutical product development, Otic may never achieve future revenue through product sales, licensing or partnership agreements. Such conditions raise substantial doubts about the Company’s ability to continue as a going concern.

From inception through September 30, 2016, the Company has raised net cash proceeds of approximately \$14.4 million from private investors through both equity and convertible debt financing to fund operating activities. As of September 30, 2016, the Company had an accumulated deficit of \$12.9 million and \$2.4 million of cash and cash equivalents. Based upon current operating plans, Otic expects the proceeds from the Equity Financing along with net cash held by each of Tokai and Otic upon consummation of the Otic Transaction, will be sufficient to fund operations into the second half of 2018. There can be no assurance that the Otic Transaction or the Equity Financing will close. If the Otic Transaction and Equity Financing are not consummated, Otic will be required to obtain additional financing to continue operations. There can be no

[Table of Contents](#)

assurance that any such financing can be obtained by the Company, or if obtained, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company's working capital requirements until it achieves profitable operations.

Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and anticipated cash proceeds from the Otic Transaction and Equity Financing and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be obtained by the Company, or if obtained, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company's working capital requirements until it achieves profitable operations.

The balance sheet at December 31, 2015 was derived from audited financial statements, but does not include all disclosures required by U.S. generally accepted accounting principles ("GAAP"). The accompanying unaudited financial statements as of September 30, 2016 and for the nine months ended September 30, 2016 and 2015 have been prepared by Otic pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Otic believes, however, that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with Otic's audited financial statements and the notes thereto for the year ended December 31, 2015 included in this proxy statement. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2016 and results of operations for the nine months ended September 30, 2016 and 2015 and cash flows for the nine months ended September 30, 2016 and 2015 have been made. The results of operations for the nine months ended September 30, 2016 and 2015 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2016.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The consolidated financial statements reflect all adjustments which are of a normal recurring nature and, in the opinion of management, necessary to a fair statement of the results for the periods presented herein. The unaudited consolidated interim financial statements have been prepared on the same basis as the annual financial statements. These interim financial results are not necessarily indicative of the results to be expected for the year ending December 31, 2016, or for any other future annual or interim period. The accompanying unaudited consolidated financial statements should be read in conjunction with the audited financial statements and the related notes thereto included herein.

The consolidated financial statements include the accounts of the Company and its Subsidiary. Intercompany transactions and balances have been eliminated upon consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent

[Table of Contents](#)

assets and liabilities, at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates. Significant estimates in the financial statements include accrued expenses and share based compensation.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its Subsidiary. Intercompany transactions and balances have been eliminated upon consolidation.

Cash and cash equivalents

Cash equivalents consist of demand deposits in banks and other short-term, highly liquid investments with original maturities of less than three months.

Restricted cash

Restricted cash is primarily used as security for rental payments and is invested in highly liquid deposits with original maturities of less than three months.

Fair value of financial instruments

The Company measures the fair value of certain of its financial instruments on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

- Level 1—Quoted prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

At September 30, 2016 and December 31, 2015, the Company's financial instruments included cash and cash equivalents and restricted cash. As of September 30, 2016, the Company's financial instruments also included short-term convertible debt. The carrying amount of cash and cash equivalents, restricted cash and short-term convertible debt approximates fair value due to the short-term maturities of these instruments.

Property and equipment

Property and equipment are presented at cost less accumulated depreciation and amortization. Depreciation and amortization are calculated based on the straight-line method over the estimated useful lives of the related assets or terms of the related leases.

In accordance with ASC 360-10 (formerly "SFAS No. 144", "Accounting for Impairment or Disposal of Long-Lived Assets" of the FASB), Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable based on estimated future undiscounted cash flows. If so indicated an impairment loss would be recognized for the difference between the carrying amount of the asset and its fair value. As of September 30, 2016, no impairment expenses have been recorded.

[Table of Contents](#)

Convertible Notes

Convertible notes with characteristics of both liabilities and equity are classified as either debt or equity based on the characteristics of their monetary value, with convertible notes classified as debt being measured at fair value, in accordance with ASC 480-10, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity".

Net Loss Per Share

Basic loss per share is computed by dividing the net loss, as adjusted to include preferred shares dividend participation rights as well as interest accumulated on preferred shares, by the weighted average number of ordinary shares outstanding during the year. Shares and preferred shares contingently issuable for little or no cash are included in basic loss per share on an as issued basis.

Diluted loss per share is computed by dividing the net loss, as adjusted to include preferred shares dividend participation rights as well as interest accumulated on preferred shares, of preferred shares outstanding during the year as well as of preferred shares that would have been outstanding if all potentially dilutive preferred shares had been issued, by the weighted average number of ordinary shares outstanding during the year, plus the number of ordinary shares that would have been outstanding if all potentially dilutive ordinary shares had been issued, using the treasury stock method, in accordance with ASC 260-10 "Earnings per Share".

Potentially dilutive shares were excluded from the calculation of diluted loss per share for all periods presented due to their anti-dilutive effect.

The following common share equivalents outstanding as of September 30, 2016 and 2015 were excluded from the computation of diluted net loss per share for the nine months ended September 30, 2016 and 2015 because they had an anti-dilutive impact:

	September 30,	
	2016	2015
Stock options	1,096,079	179,025
Stock warrants	1,942,908	1,656,473
Total	<u>3,038,987</u>	<u>1,835,498</u>

Recognition of expenses in outsourced contracts

Pursuant to management's assessment of the services that have been performed on OP-01 and OP-02 clinical trials and other contracts, the Company recognizes expense as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period; (2) measurement of progress prepared internally and/or provided by the third-party service provider; (3) analyses of data that justify the progress; and (4) management's judgment. Several of the Company's contracts extend across multiple reporting periods.

Research and development expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits and other overhead expenses, clinical trials, contract services and other outsourced contracts. Research and development expenses are charged to operations as they are incurred. Up-front payments to collaborators made in exchange for the avoidance of potential future milestone and royalty payments on licensed technology are also charged to research and development expense

[Table of Contents](#)

when the drug is still in the development stage, has not been approved by the FDA for commercialization and has no alternative uses.

The Company assesses its obligations to make milestone payments that may become due under licensed or acquired technology to determine whether the payments should be expensed or capitalized. The Company charges milestone payments to research and development expense when:

- The technology is in the early stage of development and has no alternative uses;
- There is substantial uncertainty regarding the future success of the technology or product;
- There will be difficulty in completing the remaining development; and
- There is substantial cost to complete the work.

Acquired contractual rights. Payments to acquire contractual rights to a licensed technology or drug candidate are expensed as incurred when there is uncertainty in receiving future economic benefits from the acquired contractual rights. The Company considers the future economic benefits from the acquired contractual rights to a drug candidate to be uncertain until such drug candidate is approved by the FDA or when other significant risk factors are abated.

Share-based compensation

The Company grants options and restricted stock awards to purchase the Company's common stock to employees, directors and consultants under stock option plans. The benefits provided under these plans are share-based payments that the Company accounts for using the fair value method.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model ("Black-Scholes model") that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on the historical volatility of the Company's common stock valuation and other factors. The expected terms of options granted are based on analyses of historical employee termination rates and option exercises. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant. Since the Company does not expect to pay dividends on common stock in the foreseeable future, it estimated the dividend yield to be 0%.

Share-based compensation expense recognized during a period is based on the value of the portion of share-based payment awards that is ultimately expected to vest and is amortized under the straight-line attribution method. As share-based compensation expense recognized in the accompanying consolidated statements of operations for the nine months ended September 30, 2016 and 2015 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The fair value method requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates forfeitures based on historical experience. Changes to the estimated forfeiture rate are accounted for as a cumulative effect of change in the period the change occurred.

Table of Contents

Total compensation expense related to all of the Company's share-based awards for the nine months ended September 30, 2016 and 2015 was comprised of the following (in thousands):

	Nine Months Ended September 30,	
	2016	2015
Share-based compensation classified as:		
Research and development expense	\$ 52	\$ 7
General and administrative expense	90	24
Total	<u>\$ 142</u>	<u>\$ 31</u>

	Nine Months Ended September 30,	
	2016	2016
Share-based compensation expense from:		
Stock options	\$ 141	\$ 24
Restricted stock awards	1	7
Total	<u>\$ 142</u>	<u>\$ 31</u>

Since the Company has a net operating loss carry-forward as of September 30, 2016 and 2015, no excess tax benefits for tax deductions related to share-based awards were recognized in the accompanying consolidated statements of operations.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards update ("ASU") 2014-09, "Revenue from Contracts with Customers," requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes the revenue recognition requirements in ASC 605, Revenue Recognition. This guidance is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. This guidance can be adopted either retrospectively to each prior reporting period presented, or retrospectively with a cumulative-effect adjustment recognized as of the date of adoption. The original effective date of this guidance for public entities was for annual reporting period beginning after December 15, 2016.

In August 2014, the FASB issued ASU NO. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASU 2014-15. ASU 2014-15 requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. Certain disclosures will be required if conditions give rise to substantial doubt about an entity's ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company does not anticipate an early adoption, and is currently evaluating the impact on its financial statements upon the adoption of this guidance.

[Table of Contents](#)

In January 2016, the FASB issued an amended standard requiring changes to recognition and measurement of certain financial assets and liabilities. The standard primarily affects equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. This standard is effective beginning in the first quarter of 2018. Certain provisions allow for early adoption. The Company does not expect that the adoption of this standard will have a significant impact on the financial position or results of operations.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the impact on its financial statements upon the adoption of this guidance.

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-09, Compensation – Stock Compensation (Topic 718). This guidance identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This guidance is effective for annual reporting period beginning after December 15, 2016, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the impact on its financial statements upon the adoption of this guidance.

In June 2016, the FASB issued a new standard requiring measurement and recognition of expected credit losses on certain types of financial instruments. The new standard also modifies the impairment model for available-for-sale debt securities and provides for a simplified accounting model for purchased financial assets with credit deterioration since their origination. This standard is effective beginning in the first quarter of 2020; early adoption is permitted starting from the first quarter of 2019. The Company does not expect that the adoption of this standard will have a significant impact on the financial position or results of operations.

Note 3. Convertible Loan

On July 11, 2016, OrbiMed Israel Partners Limited Partnership and Peregrine Management II Ltd. provided Otic with a convertible bridge financing in the aggregate amount of \$2,930,000 (the “Bridge Financing Amount”), pursuant to a Bridge Financing Agreement, dated July 11, 2016 (the “Bridge Financing Agreement”). Under the terms of the Bridge Financing Agreement, other than upon occurrence of an Event of Default (as defined in the Bridge Financing Agreement), Otic is not required to repay the Bridge Financing Amount or any portion in cash. The Bridge Financing Agreement further provides that upon a Deemed Liquidation (as defined in Otic’s Articles of Association), the Bridge Financing Amount is convertible into 606,845 Preferred C Shares of Otic at a price per share representing 85% of the Preferred C Shares’ original issue price. As such, conversion will occur upon closing of the Otic Transaction pursuant to the terms of the Bridge Financing Agreement.

The Company concluded the value of the note is predominantly based on a fixed monetary amount known at the date of issuance as represented by the 15% discount on the Company’s shares to be sold upon a Deemed Liquidation event (as defined in Otic’s Articles of Association). Accordingly, the note was classified as debt and is measured at its fair value, pursuant to the provisions of ASC 480-10, “Accounting for Certain Financial instruments with Characteristics of both Liabilities and Equity.”

[Table of Contents](#)

The fair value of the note is measured based on observable inputs as the fixed monetary value of the variable amount of shares to be issued upon conversion (Level 2 measurement).

Note 4. Computation of Net Loss per Share

Basic loss per share is computed by dividing the net loss, as adjusted to include preferred shares dividend participation rights as well as interest accumulated on preferred shares, by the weighted average number of ordinary shares outstanding during the year. Shares and preferred shares contingently issuable for little or no cash are included in basic loss per share on an as issued basis.

Diluted loss per share is computed by dividing the net loss, as adjusted to include preferred shares dividend participation rights as well as interest accumulated on preferred shares, of preferred shares outstanding during the year as well as of preferred shares that would have been outstanding if all potentially dilutive preferred shares had been issued, by the weighted average number of ordinary shares outstanding during the year, plus the number of ordinary shares that would have been outstanding if all potentially dilutive ordinary shares had been issued, using the treasury stock method, in accordance with ASC 260-10 "Earnings per Share".

Potentially dilutive shares were excluded from the calculation of diluted loss per share for all periods presented due to their anti-dilutive effect.

The loss and weighted average number of ordinary shares used in the calculation of basic loss per share are as follows (in thousands, except share and per share data):

	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Net loss available to shareholders of the company	\$ (4,140)	\$ (2,070)
Interest accumulated on preferred shares and on preferred shares contingently issuable for little or no cash	(917)	(671)
Net loss attributable to shareholders of preferred shares and to shareholders of preferred shares contingently issuable for little or no cash	4,339	2,159
Net loss used in the calculation of basic loss per share	\$ (718)	\$ (582)
Net loss per share	\$ (1.01)	\$ (0.65)
Weighted average number of ordinary shares	711,231	898,436

Because the inclusion of common share equivalents in the calculation would be anti-dilutive for all periods presented, diluted net loss per share is the same as basic net loss per share.

Note 5. Commitments and Contingencies

The following table summarizes Otis's contractual obligations as of September 30, 2016:

	Payments Due By Period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More Than 5 Years
Operating lease commitments ⁽¹⁾	\$324	\$ 171	\$ 153	\$ —	\$ —
Total ⁽²⁾⁽³⁾⁽⁴⁾	\$ 324	\$ 171	\$ 153	\$ —	\$ —

Contractual Obligations:

- (1) Operating lease commitments are comprised of the following:
 - a. An office lease for Otic Pharma, Ltd. which is located in Rehovot, Israel. The office space is leased under an operating lease through November 2016.
 - b. An office lease for Otic Pharma, Inc. which is located in Irvine, California in a 5,113 square-foot office space. The Irvine office is leased under an operating lease through September 2018.
 - c. A vehicle lease for employees located in the Rehovot, Israel office. The vehicle lease was canceled effective December 2016.
- (2) As of December 31, 2015, Otic received loans in the amount of approximately \$537,000 from the OCS designated for Otic's investments in research and development. The loans are linked to the U.S. dollar and bear annual interest of LIBOR. The loans are to be repaid out of royalties from sales of the products developed by Otic from their investments in research and development.
- (3) In November 2015, the Otic Pharma, Inc. entered into an Exclusive License Agreement with Scientific Development and Research Inc. and Otodyne Inc. (the "Licensors"). According to which the Licensors shall provide the License Technology, as defined in the Exclusive License Agreement, to the Subsidiary. In return to the Exclusive License Agreement, Otic Pharma, Inc. will pay to the Licensors a license fee in a total amount of \$600,000, and Otic issued to the Licensors 88,024 Ordinary Shares NIS 0.01 par value each. In addition, Otic Pharma, Inc. paid an additional amount of \$100,000 as a Technology Transfer Fee as defined in the Exclusive License Agreement, and future milestones and royalty payments, as defined and detailed in the Exclusive License Agreement.
- (4) On July 11, 2016, OrbiMed Israel Partners Limited Partnership and Peregrine Management II Ltd. provided Otic with a convertible bridge financing in the aggregate amount of \$2,930,000 (the "Bridge Financing Amount"), pursuant to a Bridge Financing Agreement, dated July 11, 2016 (the "Bridge Financing Agreement"). Under the terms of the Bridge Financing Agreement, other than upon occurrence of an Event of Default (as defined in the Bridge Financing Agreement), Otic is not required to repay the Bridge Financing Amount or any portion in cash. The Bridge Financing Agreement further provides that upon a Deemed Liquidation (as defined in Otic's Articles of Association), the Bridge Financing Amount is convertible into 606,845 Preferred C Shares of Otic at a price per share representing 85% of the Preferred C Shares' original issue price. As such, conversion will occur upon closing of the Otic Transaction pursuant to the terms of the Bridge Financing Agreement.

Indemnification: In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. No amounts associated with such indemnifications have been recorded to date.

Contingencies: From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual at September 30, 2016.

[Table of Contents](#)**Note 6. Shareholder's Equity****Composition:**

	September 30, 2016		September 30, 2015	
	Authorized	Issued	Authorized	Issued
	Number of shares		Number of shares	
Ordinary Shares of NIS 0.01 nominal value	8,600,118	740,215	7,000,016	612,681
Preferred A Shares NIS 0.01 nominal value	691,000	493,551	691,000	493,551
Preferred B Shares NIS 0.01 nominal value	4,327,590	2,640,711	4,327,590	2,640,711
Preferred C Shares NIS 0.01 nominal value	940,092	940,092	352,094	352,094
Receipts on account of Preferred A Shares	—	—	—	—
	<u>14,558,800</u>	<u>4,814,569</u>	<u>12,370,700</u>	<u>4,099,037</u>

Ordinary Shares:

Ordinary shares confer upon the holders thereof the right to receive notice of, participate in, and vote at general meetings of the Company. Holders also have the right to receive cash and stock dividends, if declared or upon dissolution, subject to the preferential rights of the holders of the series of preferred shares.

Preferred Shares:

Preferred shares are convertible into ordinary shares at the option of their holders, and confer upon their holders all rights accruing to holders of ordinary shares in the Company on an as converted basis. In addition, holders of Preferred Shares are entitled to preference upon a liquidation event and upon distribution of dividends, plus 8% annual interest calculated on the preferred share original issue price, as further detailed in the Company's Articles of Association. The Otic Transaction meets the criteria for a liquidation event as detailed in the Company's Articles of Association.

Interest accumulated on preferred shares for the nine months ended September 30, 2016 and 2015 was \$917 and \$671, respectively.

Receipts on account of Preferred A Shares:

On June 20, 2010, Incentive II Management Ltd. ("Incentive") provided Otic Pharma with a loan (the "Incentive Loan") under a Convertible Loan Agreement (the "Loan Agreement") between Otic Pharma and Incentive. As part of the closing of the Series B Preferred Shares Purchase Agreement in February 2012, Incentive, Otic Pharma and the Series B Investors agreed that the Incentive Loan provided by Incentive shall be convertible by Incentive into 196,714 Preferred A Shares (the "Incentive A Shares"), which conversion shall occur upon request by Incentive (the "Formal Conversion"). Until the Formal Conversion, the Incentive A Shares that are issuable to Incentive are deemed issued and outstanding and held by Incentive for all intents and purposes and the loan provided shall be deemed, for all intents and purposes, as repaid in full pursuant to its terms. As the underlying shares have not been issued as of December 31, 2015, the funds received in their regard are presented as receipts on account of shares on the Company's shareholders equity statement.

Warrants:

During the nine months ended September 30, 2016 and 2015, no warrants were issued and warrants issued and outstanding were 1,942,908 and 1,656,473, respectively.

[Table of Contents](#)

The Company expects all outstanding warrants to be exercised upon or prior to close of the Otic Transaction.

Note 6. Related Party Transactions

On July 27, 2012 and May 17, 2015, the Company entered into loan agreements with a director of the Company (together, the “Loan Agreements”). In accordance with the Loan Agreements, the Company provided to the director loans in the amount of \$42,555 and \$61,480, respectively, to purchase restricted ordinary shares of the Company totaling 83,441 shares and 58,000 shares, respectively. The loans are non-recourse loans and do not bear interest. The loans will be repaid prior to closing of the Otic Transaction.

Note 7. Subsequent Event

On December 21, 2016, the Company entered into a Share Purchase Agreement to merge with Tokai in an all-stock transaction. On a pro forma basis, based upon the number of shares of Tokai common stock to be issued in accordance with the Share Purchase Agreement, Tokai equity holders will own approximately 40% of the combined company and Otic equity holders will own approximately 60% of the combined company. The transaction has been approved by the board of directors of both companies and by the shareholders of Otic. The transaction is expected to close in the first half of 2017, subject to the approval of the stockholders of Tokai and other customary closing conditions, as detailed in the Share Purchase Agreement.

In connection with the transaction, Otic will be deemed to be the accounting acquirer and therefore the transaction will be treated as a reverse acquisition because (i) Otic security holders are expected to own approximately 60% of the voting interests of the combined company immediately following the closing of the transaction; (ii) directors appointed by Otic will hold a majority of the board seats in the combined company; and (iii) Otic management will hold all key positions in the management of the combined company.

ANNEX A: SHARE PURCHASE AGREEMENT

SHARE PURCHASE AGREEMENT

by and among

TOKAI PHARMACEUTICALS, INC.,

OTIC PHARMA, LTD.

and

SHAREHOLDERS OF OTIC PHARMA, LTD.

Dated as of December 21, 2016

A - 1

TABLE OF CONTENTS

	<u>Page</u>
ARTICLE I THE SHARE PURCHASE	A-9
1.1 Share Purchase	A-9
1.2 Closing	A-9
1.3 Closing Date Deliverables; Certain Definitions	A-10
1.4 [Intentionally omitted]	A-12
1.5 Treatment of Otic Pharma Share Options and Otic Pharma Warrants	A-12
1.6 Allocation Schedules	A-13
1.7 Withholding Rights	A-13
1.8 Additional Withholding Matters	A-13
ARTICLE II REPRESENTATIONS AND WARRANTIES OF SHAREHOLDERS	A-14
2.1 Organization, Standing	A-14
2.2 Authority, Power; No Conflict; Required Filings and Consents	A-14
2.3 Ownership of Otic Pharma Share Capital	A-15
2.4 Litigation	A-16
2.5 Brokers	A-16
2.6 Purchase for Own Account; Sophistication	A-16
2.7 Access to Information	A-16
2.8 Restricted Securities; Legends	A-16
2.9 Accredited Investor; Regulation S	A-17
2.10 No Other Representations or Warranties	A-17
ARTICLE III REPRESENTATIONS AND WARRANTIES OF OTIC PHARMA	A-17
3.1 Organization, Standing and Power	A-17
3.2 Capitalization	A-18
3.3 Subsidiaries	A-20
3.4 Authority; No Conflict; Required Filings and Consents	A-21
3.5 Financial Statements; Information Provided	A-21
3.6 No Undisclosed Liabilities	A-22
3.7 Absence of Certain Changes or Events	A-22
3.8 Taxes	A-22
3.9 Owned and Leased Real Properties	A-26
3.10 Intellectual Property	A-26
3.11 Contracts	A-27
3.12 Litigation	A-29

[Table of Contents](#)

	<u>Page</u>
3.13 Environmental Matters	A-29
3.14 Employee Benefit Plans	A-30
3.15 Compliance With Laws	A-32
3.16 Permits and Regulatory Matters	A-32
3.17 Employees	A-33
3.18 Insurance	A-36
3.19 No Fairness Opinion	A-36
3.20 Brokers; Fees and Expenses	A-36
3.21 Certain Business Relationships With Affiliates	A-36
3.22 Controls and Procedures, Certifications and Other Matters	A-36
3.23 Books and Records	A-37
3.24 Ownership of Public Company Common Stock	A-37
3.25 Privacy and Data Security	A-37
3.26 Government Funding	A-38
3.27 Export Control Laws	A-38
3.28 No Other Representations or Warranties	A-39
ARTICLE IV REPRESENTATIONS AND WARRANTIES OF PUBLIC COMPANY	A-39
4.1 Organization, Standing and Power	A-39
4.2 Capitalization	A-40
4.3 Subsidiaries	A-41
4.4 Authority; No Conflict; Required Filings and Consents	A-42
4.5 SEC Filings; Financial Statements; Information Provided	A-43
4.6 No Undisclosed Liabilities	A-44
4.7 Absence of Certain Changes or Events	A-44
4.8 Taxes	A-44
4.9 Owned and Leased Real Properties	A-46
4.10 Intellectual Property	A-47
4.11 Contracts	A-47
4.12 Litigation	A-49
4.13 Environmental Matters	A-49
4.14 Employee Benefit Plans	A-49
4.15 Compliance With Laws	A-52
4.16 Permits and Regulatory Matters	A-52
4.17 Employees	A-52

[Table of Contents](#)

	<u>Page</u>
4.18 Insurance	A-53
4.19 Opinion of Financial Advisor	A-53
4.20 Section 203 of the DGCL	A-53
4.21 Brokers; Fees and Expenses	A-53
4.22 Controls and Procedures, Certifications and Other Matters	A-54
4.23 Books and Records	A-54
4.24 No Other Representations or Warranties	A-54
ARTICLE V CONDUCT OF BUSINESS	A-54
5.1 Covenants of Otic Pharma	A-54
5.2 Covenants of Public Company	A-57
5.3 Confidentiality	A-59
ARTICLE VI ADDITIONAL AGREEMENTS	A-59
6.1 No Solicitation	A-59
6.2 Proxy Statement	A-62
6.3 NASDAQ Listing	A-63
6.4 Access to Information	A-63
6.5 Stockholder Approval	A-64
6.6 Legal Conditions to Transaction	A-64
6.7 Public Disclosure	A-64
6.8 Affiliate Legends	A-65
6.9 Indemnification	A-65
6.10 Notification of Certain Matters	A-66
6.11 Corporate Identity	A-66
6.12 Succession	A-66
6.13 Board of Directors of Public Company	A-66
6.14 Employee Communications	A-67
6.15 State Takeover Laws	A-67
6.16 Security Holder Litigation	A-67
6.17 Lock-Up; Regulation S	A-67
ARTICLE VII CONDITIONS TO TRANSACTION	A-68
7.1 Conditions to Each Party's Obligation To Effect the Transaction	A-68
7.2 Additional Conditions to the Obligations of Public Company	A-68
7.3 Additional Conditions to the Obligations of Otic Pharma	A-69

[Table of Contents](#)

	<u>Page</u>
ARTICLE VIII TERMINATION AND AMENDMENT	A-70
8.1 Termination	A-70
8.2 Effect of Termination	A-71
8.3 Fees and Expenses	A-72
8.4 Amendment	A-73
8.5 Extension; Waiver	A-73
8.6 Procedure for Termination, Amendment, Extension or Waiver	A-73
ARTICLE IX MISCELLANEOUS	A-73
9.1 Non-survival of Representations, Warranties and Agreements	A-73
9.2 Notices	A-73
9.3 Entire Agreement	A-74
9.4 No Third Party Beneficiaries	A-75
9.5 Assignment	A-75
9.6 Severability	A-75
9.7 Counterparts and Signature	A-75
9.8 Interpretation	A-75
9.9 Governing Law	A-75
9.10 Remedies	A-76
9.11 Submission to Jurisdiction	A-76
9.12 WAIVER OF JURY TRIAL	A-76
9.13 Disclosure Schedule	A-76
Exhibit A Form of Public Company Support Agreement	
Exhibit B Preliminary Closing Date Allocation Schedule	
Exhibit C OCS Undertaking	

TABLE OF DEFINED TERMS

Terms	Cross Reference in Agreement
102 Plan	Section 3.8(k)
102 Trustee	Section 1.3(c)
104H Ruling	Section 1.8(c)(ii)
104H Trustee	Section 1.3(c)
Acquisition Proposal	Section 6.1(f)
Adjusted Warrant	Section 1.5
Affiliate	Section 3.2(e)
Aggregate Closing Consideration Agreement	Section 1.3(c)
Alternative Acquisition Agreement	Preamble
Bankruptcy and Equity Exception	Section 6.1(b)(ii)
Business Day	Section 2.2(a)
Certificate	Section 1.2
Closing	Section 1.3(c)
Closing Date	Section 1.2(a)
Closing Date Allocation Schedule	Section 1.2(a)
Code	Section 1.3(c)
Confidentiality Agreement	Section 1.3(c)
Contract	Section 5.3
DGCL	Section 3.11(f)
Employee Benefit Plan	Section 3.5(c)
Environmental Law	Section 3.14(n)(i)
ERISA	Section 3.13(d)
ERISA Affiliate	Section 1.3(c)
Exchange Act	Section 1.3(c)
Exchange Ratio	Section 3.5(b)
Export Approvals	Section 1.6
FDA	Section 3.27(a)
Financial Statements	Section 3.16(a)
GAAP	Section 3.5(a)
Governmental Entity	Section 3.5(a)
Government Grants	Section 1.3(c)
Hazardous Substance	Section 3.26
Indemnified Persons	Section 3.13(e)
Innovation Law	Section 6.9(a)
Intellectual Property	Section 3.26
Interim Options Tax Ruling	Section 3.10(e)(i)
IRS	Section 1.8(c)(i)
Israeli Income Tax Ordinance	Section 3.14(f)
Israeli Options Tax Ruling	Section 1.3(c)
Israeli Severance Pay Law	Section 1.8(c)(i)
Israeli Tax Rulings	Section 3.17(e)
ITA	Section 1.8(c)(ii)
Liens	Section 1.3(c)
Most Recent Balance Sheet Date	Section 3.4(b)
NASDAQ	Section 3.5(a)
NASDAQ Listing Application	Section 3.5(c)
NASDAQ Proposal	Section 4.4(c)
	Section 6.3

[Table of Contents](#)

<u>Terms</u>	<u>Cross Reference in Agreement</u>
OCS	Section 3.26
Ordinary Course of Business	Section 3.3(d)
Otic Pharma	Preamble
Otic Pharma Authorizations	Section 3.16(b)
Otic Pharma Balance Sheet	Section 3.5(a)
Otic Pharma Board	Section 1.3(c)
Otic Pharma Share Capital	Section 1.3(c)
Otic Pharma Ordinary Shares	Section 2.1(b)(ii)
Otic Pharma Disclosure Schedule	Article III
Otic Pharma Employee Plans	Section 3.14(a)
Otic Pharma Insurance Policies	Section 3.18
Otic Pharma Intellectual Property	Section 3.10(b)
Otic Pharma Leases	Section 3.9(b)
Otic Pharma Material Adverse Effect	Section 3.1
Otic Pharma Organizational Documents	Section 1.3(c)
Otic Pharma Preferred Shares	Section 1.3(c)
Otic Pharma Sites	Section 3.25(a)
Otic Pharma Share Options	Section 2.3(a)
Otic Pharma Share Plan	Section 2.3(a)
Otic Pharma Third Party Intellectual Property	Section 3.10(b)
Otic Pharma Termination Fee	Section 8.3(b)
Otic Pharma Voting Proposal	Section 3.4(a)
Otic Pharma Warrants	Section 3.2(d)
Outside Date	Section 8.1(b)
Patent Rights	Section 3.10(e)(ii)
Payee	Section 1.8(a)
Paying Agent	Section 1.3(c)
Payor	Section 1.7
Permits	Section 3.16(a)
Personal Information	Section 3.25(b)
Piper	Section 3.20
Preliminary Closing Date Allocation Schedule	Section 1.3(c)
Privacy Laws	Section 3.25(b)
Proxy Statement	Section 3.5(c)
Public Company	Preamble
Public Company Authorizations	Section 4.16(a)
Public Company Balance Sheet	Section 4.5(b)
Public Company Board	Section 1.3(c)
Public Company Board Recommendation Change	Section 6.1(b)(i)
Public Company Common Stock	Section 2.1(c)
Public Company ESPP	Section 4.2(b)
Public Company Disclosure Schedule	Article IV
Public Company Employee Plans	Section 4.14(a)
Public Company Financial Advisor	Section 4.19
Public Company Insurance Policies	Section 4.18
Public Company Intellectual Property	Section 4.10(b)
Public Company Leases	Section 4.9(b)
Public Company Material Adverse Effect	Section 4.1
Public Company Meeting	Section 3.5(c)
Public Company Preferred Stock	Section 4.2(a)

[Table of Contents](#)

<u>Terms</u>	<u>Cross Reference in Agreement</u>
Public Company SEC Reports	Section 4.5(a)
Public Company Support Agreement	Preamble
Public Company Stockholder Approval	Section 3.5(c)
Public Company Stock Options	Section 4.2(b)
Public Company Stock Plans	Section 4.2(b)
Public Company Termination Fee	Section 8.3(c)
Public Company Third Party Intellectual Property	Section 4.10(b)
Public Company Voting Proposal	Section 3.5(c)
Public Company Warrants	Section 4.2(c)
Qualified Person	Section 6.1(f)
Recommendation Change Notice	Section 6.1(b)
Regulating Authority	Section 3.16(a)
Regulation S Shareholder	Section 2.9
Representatives	Section 6.1(a)
Rule 145 Affiliates	Section 6.8
SEC	Section 3.4(c)
Section 102(b)(2)	Section 1.8(c)(i)
Section 14 Arrangement	Section 3.17(e)
Section 3(i)	Section 1.8(c)(i)
Securities Act	Section 2.8(a)
Shareholders	Preamble
Specified Time	Section 6.1(f)
Subsidiary	Section 3.3(a)
Superior Proposal	Section 6.1(f)
Taxes	Section 3.8(a)
Tax Returns	Section 3.8(a)
Trademarks	Section 3.8(a)
Transaction	Section 3.10(e)(iii)
Valid Certificate	Preamble
VAT	Section 1.8(a)
Withholding Drop Date	Section 3.8(n)
	Section 1.8(a)

SHARE PURCHASE AGREEMENT

THIS SHARE PURCHASE AGREEMENT (this "Agreement"), dated as of December 21, 2016, is entered into by and among Tokai Pharmaceuticals, Inc., a Delaware corporation ("Public Company"), Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("Otic Pharma"), and the shareholders of Otic Pharma identified on the signature page hereto (the "Shareholders").

WHEREAS, the Shareholders own all of the issued and outstanding shares of Otic Pharma Share Capital;

WHEREAS, the parties desire to enter into this Agreement pursuant to which each Shareholder agrees to sell to Public Company and Public Company agrees to purchase from each Shareholder all of the shares of Otic Pharma Share Capital owned by such Shareholder (the "Transaction"), on the terms and subject to the conditions contained herein; and

WHEREAS, concurrently with the execution and delivery of this Agreement and as a condition and inducement to the Shareholders' and Otic Pharma's willingness to enter into this Agreement, the stockholders of Public Company listed on Section A of the Public Company Disclosure Schedule have entered into Support Agreements, dated as of the date of this Agreement, in the form attached hereto as Exhibit A (the "Public Company Support Agreements"), pursuant to which such stockholders have, subject to the terms and conditions set forth therein, agreed to vote all of their shares of capital stock of Public Company in favor of the Transaction and against any competing proposals.

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth below, Public Company, the Shareholders and Otic Pharma, intending to be legally bound, agree as follows:

ARTICLE I

THE SHARE PURCHASE

1.1 Share Purchase. Upon the terms and subject to the conditions set forth in this Agreement, on the Closing Date Public Company shall purchase from each Shareholder, and each Shareholder shall, severally and not jointly, sell, convey, assign, transfer and deliver to Public Company, all of the Otic Pharma Share Capital owned by such Shareholder, as set forth opposite such Shareholder's name on the Closing Date Allocation Schedule, free and clear of all Liens. Each Shareholder hereby waives any rights of pre-emption, rights of first refusal or other restrictions on transfer of the Otic Pharma Share Capital whether conferred by the Otic Pharma Organizational Documents or otherwise, in respect of the transfers contemplated by this Agreement.

1.2 Closing.

(a) Subject to the satisfaction or waiver (to the extent permitted by law) of the conditions set forth in Article VII, the closing of the Transaction (the "Closing") will take place at 10:00 a.m., Eastern time, on a date to be specified by Public Company and Otic Pharma (the "Closing Date"), which shall be no later than the second Business Day after satisfaction or waiver of the conditions set forth in Article VII (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the fulfillment or waiver of such conditions), at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109, unless another date, place or time is agreed to in writing by Public Company and Otic Pharma. For the purposes of this Agreement, the term "Business Day" shall mean any day other than a Friday, Saturday, Sunday or other day on which commercial banking institutions in New York, New York or Tel Aviv, Israel are authorized or permitted by law to be closed.

[Table of Contents](#)

(b) At the Closing:

(i) Otic Pharma and the Shareholders shall deliver to Public Company the various certificates, instruments and documents referred to in Section 7.2;

(ii) Public Company shall deliver to Otic Pharma the various certificates, instruments and documents referred to in Section 7.3;

(iii) Public Company shall deliver the consideration contemplated by Section 1.3(b); and

(iv) each Shareholder shall deliver or procure to be delivered to Public Company:

(A) duly executed share transfer deeds in favor of Public Company in respect of all shares of Otic Pharma Share Capital owned by such Shareholder, together with Certificates in respect of such shares, or if any Certificate shall have been lost, stolen, destroyed or never issued, an affidavit of that fact by the person claiming such Certificate to be lost, stolen, destroyed or never issued;

(B) a copy of any power of attorney under which this Agreement or any of the transactions, transfers or documents contemplated by this Agreement is effected and/or executed by the Shareholder, and evidence of the authority of any person signing on behalf of any Shareholder that is a corporate entity; and

(C) a power of attorney appointing Public Company as its attorney in its name and on its behalf to exercise any or all of the voting and other rights, powers and privileges (including the right to nominate proxies on its behalf) attached to the shares of Otic Pharma Share Capital registered in its name and under which such Shareholder undertakes to ratify everything done by Public Company, as its attorney, in pursuance of the power of attorney, and agrees that such power of attorney is executed to secure the interest of Public Company in the Otic Pharma Share Capital and shall accordingly be irrevocable.

1.3 Closing Date Deliverables; Certain Definitions.

(a) No later than three Business Days prior to the Closing Date, Otic Pharma shall deliver to Public Company the Closing Date Allocation Schedule.

(b) On the Closing Date, Public Company shall deliver to the Shareholders, in accordance with the Closing Date Allocation Schedule, certificates representing a number of shares of common stock, \$0.001 par value per share, of Public Company ("Public Company Common Stock"), equal to the Aggregate Closing Consideration; provided, that payment hereunder in the form of shares of Public Company Common Stock shall be made only in whole shares, and any fractional shares shall be rounded down to the nearest whole share.

(c) For purposes of this Agreement, the following terms shall have the following meanings:

"102 Trustee" means Altshuler Shaham Benefits Ltd., appointed by Otic Pharma to serve as trustee pursuant to Section 102 of the Israeli Income Tax Ordinance and approved by the ITA.

"104H Trustee" means the trustee appointed by Otic Pharma in accordance with the provisions of Section 104H of the Israeli Income Tax Ordinance, and to be approved by the ITA in the 104H Ruling.

"Aggregate Closing Consideration" means an aggregate number of newly issued shares of Public Company Common Stock equal to the product of the total number of the shares of Otic Pharma Share Capital issued and outstanding and held by the Shareholders as of immediately prior to the Closing and the Exchange Ratio, which aggregate number shall in no event exceed 36,911,631.

"Certificate" means a certificate which as of immediately prior to the Closing represented outstanding shares of Otic Pharma Share Capital.

Table of Contents

“Closing Date Allocation Schedule” means a schedule, prepared by Otic Pharma in the format of the Preliminary Closing Date Allocation Schedule, dated as of the Closing Date and in form and substance reasonably acceptable to Public Company, setting forth, for each Shareholder: (a) such Shareholder’s name and address; (b) the number of shares of each class of Otic Pharma Share Capital held as of the Closing Date by such Shareholder; (c) the portion of the Aggregate Closing Consideration payable to such Shareholder in accordance with the Otic Pharma Organizational Documents; and (d) such information that is required under Treasury Regulation Section 1.6045-1 for any share of Otic Pharma Share Capital that is a covered security as defined in Treasury Regulation Section 1.6045-1(a)(15).

“Code” means the Internal Revenue Code of 1986, as amended.

“ERISA” means the Employee Retirement Income Security Act of 1974, as amended.

“ERISA Affiliate” means any entity that is, or at any applicable time was, a member of (1) a controlled group of corporations (as defined in Section 414(b) of the Code), (2) a group of trades or businesses under common control (as defined in Section 414(c) of the Code), or (3) an affiliated service group (as defined under Section 414(m) of the Code or the regulations under Section 414(o) of the Code), any of which includes or included the entity in question or any of its Subsidiaries.

“Governmental Entity” means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental or private body exercising any regulatory, Taxing or other governmental or quasi-governmental authority (including any governmental division, department, agency, commission, instrumentality, official, organization, unit, body or entity and any court or other tribunal).

“Israeli Income Tax Ordinance” means the Israeli Income Tax Ordinance (New Version) 1961 and the regulations and rules promulgated thereunder.

“ITA” means the Israeli Tax Authority.

“Otic Pharma Board” means the Board of Directors of Otic Pharma.

“Otic Pharma Ordinary Shares” means Ordinary Shares, NIS 0.01 nominal value per share, of Otic Pharma.

“Otic Pharma Organizational Documents” means the Articles of Association of Otic Pharma.

“Otic Pharma Preferred Shares” means, collectively, the Series A Preferred Shares, Series B Preferred Shares and Series C Preferred Shares.

“Otic Pharma Share Capital” means Otic Pharma Ordinary Shares and Otic Pharma Preferred Shares, collectively.

“Paying Agent” means the Public Company, or such other entity or Person as may be mutually agreed by the Public Company and Otic Pharma.

“Preliminary Closing Date Allocation Schedule” means the schedule attached hereto as Exhibit B and dated as of the date hereof, setting forth, for each Shareholder: (a) such Shareholder’s name and address; (b) the number of shares of each class of Otic Pharma Share Capital expected to be held as of the Closing Date by such Shareholder; (c) the portion of the Aggregate Closing Consideration payable to such Shareholder in accordance with the Otic Pharma Organizational Documents; (d) such information that is required under Treasury Regulation Section 1.6045-1 for any share of Otic Pharma Share Capital that is a covered security as defined in Treasury Regulation Section 1.6045-1(a)(15).

[Table of Contents](#)

“Public Company Board” means the Board of Directors of Public Company.

“Representatives” means, with respect to any entity, the directors, officers, employees, financial advisors, attorneys, accountants, consultants, agents and other authorized representatives of such entity, acting in such capacity.

“Series A Preferred Shares” means the Series A Preferred Shares, NIS 0.01 nominal value per share, of Otic Pharma.

“Series B Preferred Shares” means the Series B Preferred Shares, NIS 0.01 nominal value per share, of Otic Pharma.

“Series C Preferred Shares” means the Series C Preferred Shares, NIS 0.01 nominal value per share, of Otic Pharma.

1.4 [Intentionally omitted]

1.5 Treatment of Otic Pharma Share Options and Otic Pharma Warrants.

(a) At the Closing, each outstanding option to purchase Otic Pharma Ordinary Shares (each, a “Otic Pharma Share Option” and collectively, the “Otic Pharma Share Options”), whether vested or unvested, and the Otic Pharma Ltd. Global Share Incentive Plan (2012) (the “Otic Pharma Share Plan”) itself, insofar as it relates to outstanding Otic Pharma Share Options, shall be assumed by Public Company and shall become an option to acquire, on the same terms and conditions as were applicable under such Otic Pharma Share Option immediately prior to the Closing, such number of shares of Public Company Common Stock as is equal to the number of shares of Otic Pharma Ordinary Shares subject to the unexercised portion of such Otic Pharma Share Option immediately prior to the Closing multiplied by the Exchange Ratio (rounded down to the nearest whole share number), at an exercise price per share equal to the exercise price per share of such Otic Pharma Share Option immediately prior to the Closing divided by the Exchange Ratio (rounded up to the nearest whole cent); provided that the assumption of each Otic Pharma Share Option pursuant to this Section 2.3(a) shall comply with all requirements of Sections 424 and 409A of the Code and the Treasury regulations issued thereunder, as applicable, and of the Israeli Options Tax Ruling. Such Otic Pharma Share Options shall continue in effect on the same terms and conditions to which they are currently subject (subject to the adjustments required by this Section 1.5 after giving effect to the Transaction). Otic Pharma shall, prior to the Closing, take all actions necessary or desirable in connection with the treatment of Otic Pharma Share Options contemplated by this Section 1.5(a), including obtaining the consent from each holder of any Otic Pharma Share Options (unless such consent is not required under the terms of the applicable agreement, instrument or plan).

(b) As soon as practicable after the Closing, Public Company shall deliver to the participants in the Otic Pharma Share Plan appropriate notice setting forth such participants’ rights pursuant to Otic Pharma Share Options, as provided in this Section 1.5.

(c) Public Company shall take all corporate action necessary to reserve for issuance a sufficient number of shares of Public Company Common Stock for delivery upon exercise of Otic Pharma Share Options assumed in accordance with this Section 1.5. As promptly as practicable after the Closing, Public Company shall file a registration statement on Form S-8 (or any successor form) or another appropriate form with respect to the shares of Public Company Common Stock subject to such options and shall use commercially reasonable efforts to maintain the effectiveness of such registration statement or registration statements (and maintain the current status of the prospectus or prospectuses contained therein) for so long as such options remain outstanding.

(d) Otic Pharma shall terminate any employee share purchase plans in accordance with their terms as of or prior to the Closing.

[Table of Contents](#)

(e) At the Closing, by virtue of the Transaction, each Otic Pharma Warrant outstanding immediately prior to the Closing shall be automatically assumed by Public Company and shall become a warrant to acquire, on the same terms and conditions as were applicable under such Otic Pharma Warrant, such number of shares of Public Company Common Stock as is equal to the number of Otic Pharma Ordinary Shares, Series B Preferred Shares or Series C Preferred Shares, as applicable, subject to the unexercised portion of such Otic Pharma Warrant immediately prior to the Closing multiplied by the Exchange Ratio (rounded down to the nearest whole share number), at an exercise price per share equal to the exercise price per share of such Otic Pharma Warrant immediately prior to the Closing divided by the Exchange Ratio (rounded up to the nearest whole cent) (each, as so adjusted, an “Adjusted Warrant”). Otic Pharma shall, prior to the Closing, take all actions necessary or desirable in connection with the treatment of Otic Pharma Warrants contemplated by this Section 2.3(e). Public Company shall take all corporate actions necessary to reserve for issuance of shares of Public Company Common Stock that will be subject to the Adjusted Warrants.

(f) For purposes of this Section 1.5, “Exchange Ratio” means 4.255.

1.6 Allocation Schedules.

(a) The Preliminary Closing Date Allocation Schedule sets forth a good faith estimate as of the date of this Agreement of the amounts payable to the Shareholders pursuant to this Agreement. Otic Pharma shall deliver to Public Company, at least three Business Days prior to the Closing, the Closing Date Allocation Schedule. Public Company shall be entitled to rely conclusively on the Closing Date Allocation Schedule, and, as between the Shareholders, on the one hand, and Public Company, on the other hand, any amounts delivered by the Public Company to any Shareholder in accordance with the Closing Date Allocation Schedule shall be deemed for all purposes to have been delivered to the applicable Shareholder in full satisfaction of the obligations of the Public Company under this Article I.

(b) Public Company shall pay the portion of the Aggregate Closing Consideration payable in respect of the Otic Pharma Share Capital to the applicable Shareholders in accordance with the Closing Date Allocation Schedule.

1.7 Withholding Rights. Subject to the provisions of Section 1.8, each of Otic Pharma, Public Company, the Paying Agent and the 102 Trustee (each, a “Payor”) will be entitled to deduct and withhold from the amounts otherwise payable by it pursuant to this Agreement to any person such amounts as it reasonably determines that it is required to deduct and withhold with respect to the making of such payment under the Israeli Income Tax Ordinance, the Code, or any other applicable law, including the Israeli Income Tax Ordinance and to collect any necessary Tax forms, including Forms W-8 or W-9, as applicable, or any similar information, from Shareholders and any other recipients of payments hereunder. In the event that any amount is so deducted and withheld, and properly remitted to the applicable Tax authority, such amount will be treated for all purposes of this Agreement as having been paid to the person to whom the payment from which such amount was withheld was made. The Public Company undertakes to promptly provide each of the Shareholders from whom Tax was so withheld with sufficient evidence regarding the amounts that were paid and withheld with respect to such Shareholders.

1.8 Additional Withholding Matters.

(a) Notwithstanding Section 1.7 above, with respect to Israeli Tax, no amount payable to a Shareholder or to a holder of Otic Pharma Share Options (each a “Payee”) under this Agreement at the Closing shall be subject to withhold of Israeli Tax if the 104H Ruling has been received.

(b) To the extent not previously filed, Otic Pharma shall cause its Israeli counsel in full coordination with Public Company and its Israeli counsel, to prepare and file with the ITA an application for the following rulings:

(i) A ruling in relation to the Otic Pharma Share Capital subject to the provisions of Section 102(b)(2) of the Israeli Income Tax Ordinance (“Section 102(b)(2)”) and Otic Pharma Share Options subject to

[Table of Contents](#)

the provisions of Section 102(b)(2) or Section 3(i) of the Israeli Income Tax Ordinance (“[Section 3\(i\)](#)”), as applicable, confirming, among others, that: (i) the assumption of the Otic Share Option Plan, and of the Otic Pharma Share Capital and Otic Pharma Share Options, which remain subject to the statutory minimum trust period under such Section 102 of the Israeli Income Tax Ordinance, will not constitute a violation of the requirements of Section 102 of the Israeli Income Tax Ordinance; and (ii) Public Company and anyone acting on its behalf, including the Paying Agent, shall be exempt from withholding Tax in relation to any payments or consideration transferred to the 102 Trustee in relation to Otic Pharma Share Capital subject to Section 102(b)(2) or Otic Pharma Share Options subject to Section 102(b)(2) or Section 3(i), as applicable; which ruling may be subject to customary conditions regularly associated with such a ruling (the “[Israeli Options Tax Ruling](#)”). If the Israeli Options Tax Ruling is not granted prior to the Closing, Otic Pharma shall seek to receive prior to the Closing an interim tax ruling confirming among others that Public Company and anyone acting on its behalf (including the Paying Agent) shall be exempt from Israeli withholding Tax in relation to any payments made to the 102 Trustee with respect to Otic Pharma Share Capital subject to Section 102(b)(2) or Otic Pharma Share Options subject to Section 102(b)(2) or Section 3(i) (which interim tax ruling may be subject to customary conditions regularly associated with such an interim tax ruling) (the “[Interim Options Tax Ruling](#)”); and

(ii) A ruling confirming that the provisions of Section 104H apply to the Transaction and that the applicable Israeli Tax with respect to the Transaction shall be deferred in accordance with the provisions of Section 104H (the “[104H Ruling](#)” and together with the Interim Options Tax Ruling and the Israeli Options Tax Rulings, the “[Israeli Tax Rulings](#)”).

(c) The parties will cause their respective Israeli counsel, advisors and accountants to coordinate and cooperate and provide all information required with respect to Otic Pharma’s preparation and filing of such application and in the preparation of any written or oral submissions that may be necessary, proper or advisable to obtain the Israeli Tax Rulings. Subject to the terms and conditions hereof, Otic Pharma shall use commercially reasonable efforts to promptly take, or cause to be taken, all reasonable action and to do, or cause to be done, all reasonable things necessary, proper or advisable to obtain the Israeli Tax Rulings as promptly as practicable; provided, however, that if none of such Israeli Tax Rulings is obtained for any reason whatsoever by the Closing Date, the Closing shall be delayed or postponed. For the avoidance of doubt, it is clarified that the language of the Israeli Tax Rulings (as applicable) shall be subject to the prior written approval of Public Company and its Israeli counsel, which shall not be unreasonably withheld or delayed. Otic Pharma will inform Public Company and its Israeli counsel in advance of any meeting or other discussion with the ITA with respect to any of the Israeli Tax Rulings and allow Public Company’s counsel to attend such meeting and participate in such discussions. Should Public Company’s counsel not attend any such meeting or discussion with the ITA, the counsel of Otic Pharma shall provide such counsel with an update of such meeting or discussion within one (1) Business Day of such meeting or discussion.

ARTICLE II

REPRESENTATIONS AND WARRANTIES OF SHAREHOLDERS

Each Shareholder, severally and not jointly, represents and warrants to Public Company that the statements contained in this [Article II](#) are true and correct.

2.1 **Organization, Standing.** To the extent such Shareholder is an entity, (a) the Shareholder is a corporation or other entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation and (b) the Shareholder is not in default under or in violation of any provision of its organizational documents. The Shareholder has all requisite power and authority to carry on the businesses in which it is engaged and to own and use the properties owned and used by it.

2.2 **Authority, Power, No Conflict, Required Filings and Consents.**

(a) Except as set forth in [Section 2.2\(a\)](#) of the Otic Pharma Disclosure Schedule, the Shareholder has all requisite power and authority and capacity (in the case of individuals) to execute and deliver this Agreement

Table of Contents

and the other agreements contemplated hereby to which the Shareholder is a party and to perform the Shareholder's obligations hereunder and thereunder. The execution and delivery by the Shareholder of this Agreement and the other agreements contemplated hereby to which the Shareholder is a party and the performance by the Shareholder of this Agreement and the consummation by the Shareholder of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate and other action on the part of the Shareholder. This Agreement and all other agreements contemplated hereby to which the Shareholder is a party have been or will be as of the Closing Date duly and validly executed and delivered by the Shareholder and, assuming the due authorization, execution and delivery by Public Company, Otic Pharma, the other Shareholders, and any other party thereto, constitutes or will constitute a valid and binding obligation of the Shareholder, enforceable against the Shareholder in accordance with its terms, subject to applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equity principles (the "Bankruptcy and Equity Exception").

(b) The execution and delivery of this Agreement by the Shareholder does not, and the consummation by the Shareholder of the Transaction shall not, (i) conflict with, or result in any violation or breach of, any provision of the certificate of incorporation or bylaws (or similar organizational documents) of Shareholder (to the extent Shareholder is an entity), (ii) conflict with, or result in any violation or breach of, or constitute (with or without notice or lapse of time, or both) a default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit) under, or require a consent or waiver under, constitute a change in control under, require the payment of a penalty under or result in the imposition of any mortgage, security interest, pledge, lien, charge or encumbrance of any nature ("Liens") on assets under any of the terms, conditions or provisions of any note, bond, mortgage, indenture, lease, license, contract or other agreement, instrument or obligation to which the Shareholder is a party or by which any of its properties or assets may be bound, or (iii) conflict with or violate any permit, concession, franchise, license, judgment, injunction, order, decree, statute, law, ordinance, rule or regulation applicable to the Shareholder or any of its properties or assets, except in the case of clauses (ii) and (iii) of this Section 2.2(b), for any such conflicts, violations, breaches, defaults, terminations, cancellations, accelerations or losses that, individually or in the aggregate, are not reasonably likely to prohibit or materially delay the ability of the Shareholder to consummate the transactions contemplated by this Agreement or to perform its obligations hereunder. Section 2.2(b) of the Otic Pharma Disclosure Schedule lists all consents, waivers and approvals (if any) under any of the Shareholder's agreements, licenses or leases required to be obtained in connection with the consummation of the transactions contemplated by this Agreement, which, if individually or in the aggregate were not obtained, would reasonably be expected to prohibit or materially delay the ability of the Shareholder to consummate the transactions contemplated by this Agreement or to perform its obligations hereunder.

(c) No consent, approval, license, permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity is required by or with respect to the Shareholder in connection with the execution and delivery of this Agreement by the Shareholder or the consummation by the Shareholder of the transactions contemplated by this Agreement, except for such consents, authorizations, orders, filings, approvals and registrations that, individually or in the aggregate, if not obtained or made, would reasonably be expected to prohibit or materially delay the ability of the Shareholder to consummate the transactions contemplated by this Agreement or to perform its obligations hereunder.

2.3 Ownership of Otic Pharma Share Capital. The Shareholder holds legally, beneficially and of record all of the Shareholder's Otic Pharma Share Capital set forth on Section 3.2(b) of the Otic Pharma Disclosure Schedule, free and clear of any Liens (other than restrictions on transfer arising under applicable securities laws). Except as set forth in Section 2.3 and Section 3.2(e) of the Otic Pharma Disclosure Schedule, the Shareholder is not a party to any voting trust, proxy, or other agreement or understanding with respect to the voting or transfer of any Shares. Upon consummation of the purchase contemplated hereby, Public Company will acquire from the Shareholder good and marketable title to all Shares owned by the Shareholder, free and clear of all Liens (other than restrictions on transfer arising under applicable securities laws).

Table of Contents

2.4 Litigation. There is no action, suit, proceeding, claim, arbitration or investigation before any Governmental Entity or before any arbitrator that is pending or has been threatened in writing against the Shareholder that questions the validity of this Agreement or any action taken or to be taken by the Shareholder in connection herewith or that would reasonably be expected to prohibit or materially delay the Shareholder's ability to consummate the transactions contemplated by this Agreement. The Shareholder does not have any claim of any kind against Otic Pharma.

2.5 Brokers. The Shareholder has no liability or obligation to pay any fees or commissions to any broker, finder or agent with respect to the transactions contemplated by this Agreement.

2.6 Purchase for Own Account; Sophistication. The Shareholder acknowledges and agrees that shares of Public Company Common Stock to be acquired by the Shareholder pursuant to this Agreement will be acquired for investment for the Shareholder's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Shareholder has no present intention of selling, granting any participation in, or otherwise distributing the same. The Shareholder acknowledges and agrees that the Shareholder does not presently have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third party, with respect to any of the shares of Public Company Common Stock to be received by it pursuant to this Agreement. The Shareholder represents and warrants that it has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of owning the shares of Public Company Common Stock to be received by it pursuant to this Agreement. The Shareholder has the ability to bear the economic risk of the investment in shares of Public Company Common Stock, including complete loss of such investment.

2.7 Access to Information. The Shareholder acknowledges that (a) it has been afforded (i) access to information about each of Otic Pharma and Public Company, respectively, and their respective financial conditions, results of operations, businesses, properties and prospects sufficient to enable the Shareholder to evaluate its investment in Public Company Common Stock; and (ii) the opportunity to obtain such additional information that the other party possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment in Public Company Common Stock and any such additional information has been provided to the Shareholder's reasonable satisfaction, and (b) it has sought such professional advice as it has considered necessary to make an informed decision with respect to its acquisition of the Public Company Common Stock. Except to the extent expressly provided for in this Agreement, the Shareholder hereby agrees that neither Public Company nor any of its Affiliates will have or be subject to any liability or indemnification obligation to the Shareholder or to any other person resulting from the issuance of shares of Public Company Common Stock to the Shareholders.

2.8 Restricted Securities; Legends.

(a) The Shareholder understands that the shares of Public Company Common Stock to be received by it in connection with the Transaction have not been, and will not be, registered under the Securities Act of 1933, as amended (the "Securities Act"), by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Shareholder's representations and warranties as expressed herein. The Shareholder understands that such shares of Public Company Common Stock will be "restricted securities" under applicable securities laws and that, pursuant to these laws, the Shareholder must hold such shares indefinitely unless they are registered with the Securities and Exchange Commission (the "SEC") and qualified by state authorities, or an exemption from such registration and qualification requirements is available.

(b) The Shareholder understands that the shares of Public Company Common Stock to be received by it in connection with the Transaction may be notated with one or more of the following legends:

(i) "THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A

[Table of Contents](#)

VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.”

(ii) Any legend required by applicable securities laws to the extent such laws are applicable to the Shares represented by the certificate, instrument, or book entry so legended.

2.9 Accredited Investor; Regulation S. Except as set forth on Schedule 2.9 to this Agreement, the Shareholder either is (a) an “accredited investor” (as defined in Regulation D promulgated under the Securities Act) or (b) not a “U.S. person” within the meaning of Rule 902 of Regulation S of the Securities Act and is not acquiring Public Company Common Stock pursuant to this Agreement for the account or benefit of any U.S. person within the meaning of Rule 902 of Regulation S of the Securities Act (each such Shareholder, a “Regulation S Shareholder”).

2.10 No Other Representations or Warranties. The Shareholder hereby acknowledges and agrees that, except for the representations and warranties contained in this Agreement, none of Public Company nor any other person on behalf of Public Company makes any express or implied representation or warranty with respect to Public Company or with respect to any other information provided to Otic Pharma, any Shareholder or any of their Affiliates in connection with the transactions contemplated hereby, and (subject to the express representations and warranties of Public Company set forth in Article IV (in each case as qualified and limited by the Public Company Disclosure Schedule)) no Shareholder nor any of their respective Affiliates, stockholders, directors, officers, employees, agents, representatives or advisors, or any other person, has relied on any such information (including the accuracy or completeness thereof).

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF OTIC PHARMA

Otic Pharma represents and warrants to Public Company that the statements contained in this Article III are true and correct, except as expressly set forth herein or in the disclosure schedule delivered by Otic Pharma to Public Company on the date of this Agreement (the “Otic Pharma Disclosure Schedule”). For purposes hereof, the phrase “to the knowledge of Otic Pharma” and similar expressions mean the actual knowledge of the persons identified on Section K of the Otic Pharma Disclosure Schedule for this purpose, and such knowledge as such persons would reasonably be expected to have obtained in the course of their performance of their positions at Otic Pharma (but without any special investigation).

3.1 Organization, Standing and Power. Otic Pharma is a private limited company duly organized and validly existing under the laws of the State of Israel and is not a “breaching company” in the records of the Israeli Registrar of Companies. Otic Pharma has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction listed on Section 3.1 of the Otic Pharma Disclosure Schedule, which jurisdictions constitute the only jurisdictions in which the character of the properties it owns, operates or leases or the nature of its activities makes such qualification necessary, except for such failures to be so qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect. For purposes of this Agreement, the term “Otic Pharma Material Adverse Effect” means any material adverse change, effect, event, circumstance or development with respect to, or material adverse effect on, the business, assets, liabilities, capitalization, condition (financial or other), or results of operations of Otic Pharma and its Subsidiaries, taken as a whole; provided, however, that none of the following, to the extent arising after the date of this Agreement, shall be deemed to be a Otic Pharma Material Adverse Effect: any change or event caused by or resulting from (A) changes in prevailing economic or market conditions in the United States or any other jurisdiction in which

Table of Contents

such entity has substantial business operations (except to the extent those changes have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate in the relevant jurisdiction), (B) changes or events affecting the industry or industries in which Otic Pharma and its Subsidiaries operate generally (except to the extent those changes or events have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate), (C) changes in generally accepted accounting principles or requirements applicable to Otic Pharma and its Subsidiaries (except to the extent those changes or events have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate), (D) changes in laws, rules or regulations of general applicability or interpretations thereof by any Governmental Entity (except to the extent those changes or events have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate), (E) any natural disaster or any outbreak of major hostilities in which the United States or Israel is involved or any act of terrorism within the United States or Israel or directed against their facilities or citizens wherever located (except to the extent those changes or events have a disproportionate effect on Otic Pharma and its Subsidiaries relative to the other participants in the industry or industries in which Otic Pharma and its Subsidiaries operate), or (F) any failure by Otic Pharma to meet any internal guidance, budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations (but not, in the case of this clause (F), the underlying cause of such changes or failures, unless such changes or failures would otherwise be excepted from this definition). For the avoidance of doubt, the parties agree that the terms “material,” “materially” and “materiality” as used in this Agreement with an initial lower case “m” shall have their respective customary and ordinary meanings, without regard to the meanings ascribed to Otic Pharma Material Adverse Effect or Public Company Material Adverse Effect, in each case as defined in this Agreement. Otic Pharma has made available to Public Company complete and accurate copies of the Otic Pharma Organizational Documents and is not in material default under or in material violation of any provision of such documents.

3.2 Capitalization.

(a) The authorized share capital of Otic Pharma consists of 9,207,060 Ordinary Shares, of which 740,215 were issued and outstanding, and 5,958,682 Preferred Shares, of which: (i) 691,000 shares are designated as Series A Preferred Shares, of which 493,551 were issued and outstanding, (ii) 4,327,590 shares are designated as Series B Preferred Shares, of which 2,640,711 were issued and outstanding, and (iii) 1,546,950 shares are designated as Series C Preferred Shares, of which 940,092 were issued and outstanding. The rights and privileges of each class and series of Otic Pharma’s share capital are as set forth in Otic Pharma’s articles of association. As of the date of this Agreement, no shares were held in the treasury of Otic Pharma or by Subsidiaries of Otic Pharma.

(b) Section 3.2(b) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list, as of the date of this Agreement, of the holders of Otic Pharma Share Capital, showing the number of shares, and the class or series of such shares, held by each shareholder and (for shares other than Otic Pharma Ordinary Shares) the number of shares of Otic Pharma Ordinary Shares (if any) into which such shares are convertible. Section 3.2(b) of the Otic Pharma Disclosure Schedule also sets forth a complete and accurate list of all issued and outstanding shares of Otic Pharma Ordinary Shares that constitute restricted stock or that are otherwise subject to a repurchase or redemption right or right of first refusal in favor of Otic Pharma, indicating the name of the applicable shareholder, the vesting schedule for any such shares, including the extent to which any such repurchase or redemption right or right of first refusal has lapsed as of the date of this Agreement, whether (and to what extent) the vesting will be accelerated in any way by the transactions contemplated by this Agreement or by termination of employment or change in position following consummation of the transactions contemplated by this Agreement, and whether to the knowledge of Otic Pharma such holder has the sole power to vote and dispose of such shares.

(c) The Otic Pharma Ltd. Global Share Initiative Plan (2012) is the sole Otic Pharma Share Plan that Otic has ever had. Section 3.2(c) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list,

[Table of Contents](#)

as of the date of this Agreement, of: (i) the number of shares of Otic Pharma Ordinary Shares issued to date under such plan, the number of shares of Otic Pharma Ordinary Shares subject to outstanding options under such Plan and the number of shares of Otic Pharma Ordinary Shares reserved for future issuance under such Plan; and (ii) all outstanding Otic Pharma Share Options, indicating with respect to each such Otic Pharma Share Option the name of the holder thereof, the number of shares of Otic Pharma Ordinary Shares subject to such Otic Pharma Share Option, the exercise price, the date of grant and the vesting schedule, including whether (and to what extent) the vesting will be accelerated in any way by the transactions contemplated by this Agreement or by termination of employment or change in position following consummation of the Transaction, whether such Otic Pharma Share Option is intended to be an incentive stock option, whether each such Otic Pharma Share Option was granted and is subject to Tax pursuant to Section 3(i) of the Israeli Income Tax Ordinance or Section 102 of the Israeli Income Tax Ordinance and the applicable sub-section of Section 102 of the Israeli Income Tax Ordinance, and for Otic Pharma Share Options subject to Section 102(b)(2) of the Israeli Income Tax Ordinance the date of deposit of such Otic Pharma Share Option with the 102 Trustee, including also full details of the grant and the date of deposit of the respective option agreement with the 102 Trustee. Otic Pharma has made available to Public Company complete and accurate copies of the Otic Pharma Share Plan and the form of share option agreements evidencing Otic Pharma Share Options.

(d) Section 3.2(d) of the Otic Pharma Disclosure Schedule sets forth the number of shares of Otic Pharma Ordinary Shares and Otic Pharma Preferred Shares reserved for future issuance pursuant to warrants or other outstanding rights (other than Otic Pharma Share Options) to purchase shares of Otic Pharma Ordinary Shares and Otic Pharma Preferred Shares outstanding as of the date of this Agreement (such outstanding warrants or other rights, the "Otic Pharma Warrants") and the agreement or other document under which such Otic Pharma Warrants were granted and sets forth a complete and accurate list of all holders of Otic Pharma Warrants indicating the number and type of shares of Otic Pharma Share Capital subject to each Otic Pharma Warrant, and the exercise price, the date of grant and the expiration date thereof. Otic Pharma has made available to Public Company complete and accurate copies of the forms of agreements evidencing all Otic Pharma Warrants.

(e) Except (i) as set forth in this Section 3.2 and (ii) as reserved for future grants under Otic Pharma Share Plan, (A) there are no equity securities of any class of Otic Pharma, or any security exchangeable into or exercisable for such equity securities, issued, reserved for issuance or outstanding and (B) there are no options, warrants, equity securities, calls, rights, commitments or agreements of any character to which Otic Pharma is a party or by which Otic Pharma or any of its Subsidiaries is bound obligating Otic Pharma or any of its Subsidiaries to issue, exchange, transfer, deliver or sell, or cause to be issued, exchanged, transferred, delivered or sold, additional shares of capital stock or other equity interests of Otic Pharma or any security or rights convertible into or exchangeable or exercisable for any such shares or other equity interests, or obligating Otic Pharma or any of its Subsidiaries to grant, extend, accelerate the vesting of, otherwise modify or amend or enter into any such option, warrant, equity security, call, right, commitment or agreement. Otic Pharma does not have any outstanding stock appreciation rights, phantom stock, performance based rights or similar rights or obligations. Other than Otic Pharma's articles of association, neither Otic Pharma nor any of its Affiliates is a party to or is bound by any, and to the knowledge of Otic Pharma, there are no, agreements or understandings with respect to the voting (including voting trusts and proxies) or sale or transfer (including agreements imposing transfer restrictions) of any shares or other equity interests of Otic Pharma. For purposes of this Agreement, the term "Affiliate" when used with respect to any party shall mean any person who is an "affiliate" of that party within the meaning of Rule 405 promulgated under the Securities Act. Except as contemplated by this Agreement or described in this Section 3.2(e), there are no registration rights to which Otic Pharma or any of its Subsidiaries is a party or by which it or they are bound with respect to any equity security of any class of Otic Pharma.

(f) All outstanding Otic Pharma Share Capital is, and all shares of Otic Pharma Ordinary Shares subject to issuance as specified in Sections 3.2(c), 3.2(d), and 3.2(e) upon issuance on the terms and conditions specified in the instruments pursuant to which they are issuable, will be, duly authorized, validly issued, fully paid and nonassessable and not subject to or issued in violation of any purchase option, call option, right of first refusal, preemptive right, subscription right or any similar right under any provision of applicable law, the Otic

Table of Contents

Pharma Organizational Documents or any agreement to which Otic Pharma is a party or is otherwise bound. There are no obligations, contingent or otherwise, of Otic Pharma or any of its Subsidiaries to repurchase, redeem or otherwise acquire any shares of Otic Pharma Share Capital. All outstanding shares of Otic Pharma Share Capital have been offered, issued and sold by Otic Pharma in compliance with all applicable securities laws.

(g) No consent of the holders of Otic Pharma Share Options or Otic Pharma Warrants, apart from consents previously obtained, is required in connection with the actions contemplated by Section 1.5.

3.3 Subsidiaries.

(a) Section 3.3(a) of the Otic Pharma Disclosure Schedule sets forth, for each Subsidiary of Otic Pharma: (i) its name; (ii) the number and type of outstanding equity securities and a list of the holders thereof; and (iii) the jurisdiction of organization. For purposes of this Agreement, the term “Subsidiary” means, with respect to any party, any corporation, partnership, trust, limited liability company or other non-corporate business enterprise in which such party (or another Subsidiary of such party) owns or controls, directly or indirectly, securities or other ownership interests representing (A) more than 50% of the voting power of all outstanding stock or ownership interests of such entity or (B) the right to receive more than 50% of the net assets of such entity available for distribution to the holders of outstanding stock or ownership interests upon a liquidation or dissolution of such entity.

(b) Each Subsidiary of Otic Pharma is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation (to the extent such concepts are applicable in such jurisdiction), has all requisite corporate (or similar, in the case of a non-corporate entity) power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted and as currently proposed to be conducted, and is duly qualified to do business and is in good standing as a foreign corporation (to the extent such concepts are applicable) in each jurisdiction where the character of its properties owned, operated or leased or the nature of its activities makes such qualification necessary, except for such failures to be so organized, qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect. All of the outstanding shares of capital stock and other equity securities or interests of each Subsidiary of Otic Pharma are duly authorized, validly issued, fully paid, nonassessable and free of preemptive rights and all such shares (other than directors’ qualifying shares in the case of non-U.S. Subsidiaries, all of which Otic Pharma has the power to cause to be transferred for no or nominal consideration to Otic Pharma or Otic Pharma’s designee) are owned, of record and beneficially, by Otic Pharma or another of its Subsidiaries free and clear of all Liens, claims, agreements or limitations in Otic Pharma’s voting rights. There are no outstanding or authorized options, warrants, rights, agreements or commitments to which Otic Pharma or any of its Subsidiaries is a party or which are binding on any of them providing for the issuance, disposition or acquisition of any capital stock of any Subsidiary of Otic Pharma. There are no outstanding stock appreciation, phantom stock or similar rights with respect to any Subsidiary of Otic Pharma. There are no voting trusts, proxies or other agreements or understandings with respect to the voting of any capital stock of any Subsidiary of Otic Pharma.

(c) Otic Pharma has made available to Public Company complete and accurate copies of the charter, bylaws or other organizational documents of each Subsidiary of Otic Pharma.

(d) Otic Pharma does not control directly or indirectly or have any direct or indirect equity participation or similar interest in any corporation, partnership, limited liability company, joint venture, trust or other business association or entity which is not a Subsidiary of Otic Pharma. There are no obligations, contingent or otherwise, of Otic Pharma or any of its Subsidiaries to repurchase, redeem or otherwise acquire any shares of capital stock of any Subsidiary of Otic Pharma or to provide funds to or make any investment (in the form of a loan, capital contribution or otherwise) in any Subsidiary of Otic Pharma or any other entity, other than guarantees of bank obligations of Subsidiaries of Otic Pharma entered into in the ordinary course of business consistent in all material respects with past practice (as applicable to a party, the “Ordinary Course of Business”).

[Table of Contents](#)

3.4 [Authority; No Conflict; Required Filings and Consents.](#)

(a) Otic Pharma has all requisite corporate power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement by Otic Pharma have been duly authorized by all necessary corporate action on the part of Otic Pharma. This Agreement has been duly executed and delivered by Otic Pharma and constitutes the valid and binding obligation of Otic Pharma, enforceable against Otic Pharma in accordance with its terms, subject to the Bankruptcy and Equity Exception.

(b) The execution and delivery of this Agreement by Otic Pharma does not, and the consummation by Otic Pharma of the Transaction shall not, (i) conflict with, or result in any violation or breach of, any provision of the certificate of incorporation or bylaws of Otic Pharma or of the charter, bylaws or other organizational document of any Subsidiary of Otic Pharma, (ii) conflict with, or result in any violation or breach of, or constitute (with or without notice or lapse of time, or both) a default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any material benefit) under, or require a consent or waiver under, constitute a change in control under, require the payment of a penalty under or result in the imposition of any Liens on Otic Pharma's or any of its Subsidiaries' assets under any of the terms, conditions or provisions of any Contract required to be disclosed in Section 3.11(d) of the Otic Pharma Disclosure Schedules, or (iii) conflict with or violate any permit, concession, franchise, license, judgment, injunction, order, decree, statute, law, ordinance, rule or regulation applicable to Otic Pharma or any of its Subsidiaries or any of its or their properties or assets, except in the case of clauses (ii) and (iii) of this Section 3.4(b) for any such conflicts, violations, breaches, defaults, terminations, cancellations, accelerations or losses that, individually or in the aggregate, have not had, and are not reasonably likely to result in, the loss of a material benefit to, or in the creation of any material liability for, Otic Pharma. Section 3.4(b) of the Otic Pharma Disclosure Schedule lists all consents, waivers and approvals under any of Otic Pharma's or any of its Subsidiaries' agreements, licenses or leases required to be obtained in connection with the consummation of the transactions contemplated by this Agreement, which, if individually or in the aggregate were not obtained, would result in a loss of a material benefit to, or the creation of any material liability for, Otic Pharma or Public Company as a result of the Transaction.

(c) Except as set forth in Section 3.14(c) of the Otic Pharma Disclosure Schedule, no consent, approval, license, permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity is required by or with respect to Otic Pharma or any of its Subsidiaries in connection with the execution and delivery of this Agreement by Otic Pharma or the consummation by Otic Pharma of the Transaction, except for such consents, authorizations, orders, filings, approvals and registrations that, individually or in the aggregate, if not obtained or made, would not result in a loss of a material benefit to, or the creation of any material liability for, Otic Pharma or Public Company as a result of the Transaction. No publication of a prospectus in Israel is required by or with respect to Otic Pharma or any of its Subsidiaries in connection with the execution and delivery of this Agreement by Otic Pharma or the consummation by Otic Pharma of the Transaction.

3.5 [Financial Statements; Information Provided.](#)

(a) Otic Pharma has made available to Public Company correct and complete copies of the Financial Statements. The Financial Statements (i) comply as to form in all material respects with all applicable accounting requirements, (ii) were prepared in accordance with United States generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods covered thereby (except as may be indicated in the notes to such financial statements) and (iii) fairly present in all material respects the consolidated financial position of Otic Pharma and its Subsidiaries as of the dates thereof and the consolidated assets, liabilities, business, financial condition, results of its operations and cash flows for the periods indicated, consistent with the books and records of Otic Pharma and its Subsidiaries, except that the unaudited interim financial statements are subject to normal and recurring year-end adjustments, which will not be material in amount or effect and which

Table of Contents

do not contain footnotes otherwise required by GAAP. For purposes of this Agreement, “Financial Statements” means (i) the audited consolidated balance sheets and statements of income, changes in shareholders’ equity and cash flows of Otic Pharma as of the end of and for each of the last three fiscal years, and (ii) the unaudited consolidated balance sheet of Otic Pharma (the “Otic Pharma Balance Sheet”) as of September 30, 2016 (the “Most Recent Balance Sheet Date”) and the unaudited consolidated statements of income, changes in shareholders’ equity and cash flows for the nine months ended as of the Most Recent Balance Sheet Date.

(b) Deloitte, Brightman Almagor Zohar & Co., Otic Pharma’s current auditor, is and to the knowledge of Otic Pharma has been at all times since its engagement by Otic Pharma been, (x) “independent” with respect to Otic Pharma and its Subsidiaries within the meaning of Regulation S-X and (y) in compliance with subsections (g) through (l) of Section 10A of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) (to the extent applicable), and the related rules of the SEC and Public Company Accounting Oversight Board.

(c) The information to be supplied by or on behalf of Otic Pharma for inclusion in a definitive proxy statement on Schedule 14A seeking stockholder approval of the Public Company Voting Proposal (the “Proxy Statement”) to be sent to the stockholders of Public Company in connection with the meeting of Public Company’s stockholders (the “Public Company Meeting”) to consider the issuance of shares of Public Company Common Stock in the Transaction (the “Public Company Voting Proposal”) under the rules of The NASDAQ Stock Market, Inc. (“NASDAQ”) and the General Corporation Law of the State of Delaware (the “DGCL”) (the “Public Company Stockholder Approval”), which information shall be deemed to include all information about or relating to Otic Pharma and its Subsidiaries shall not, on the date the Proxy Statement is first mailed to stockholders of Public Company, or at the time of the Public Company Meeting, contain any statement that, at such time and in light of the circumstances under which it shall be made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements made in the Proxy Statement not false or misleading; or omit to state any material fact necessary to correct any statement in any earlier communication with respect to the solicitation of proxies for the Public Company Meeting that has become false or misleading.

3.6 No Undisclosed Liabilities. Otic Pharma does not have any liability that is required to be set forth on a balance sheet of Otic Pharma in accordance with GAAP, except for (a) liabilities shown on the Most Recent Balance Sheet, (b) liabilities that have arisen since the Most Recent Balance Sheet Date in the Ordinary Course of Business, (c) liabilities for transaction expenses incurred in connection with the transactions contemplated by this Agreement and (d) contractual and other liabilities incurred in the Ordinary Course of Business that are not required by GAAP to be reflected on a balance sheet.

3.7 Absence of Certain Changes or Events. During the period beginning on the Most Recent Balance Sheet Date and ending on the date hereof, Otic Pharma and its Subsidiaries have conducted their respective businesses only in the Ordinary Course of Business and, since such date, there has not been (i) any change, event, circumstance, development or effect that, individually or in the aggregate, has had, or is reasonably likely to have, a Otic Pharma Material Adverse Effect; or (ii) any other action that would have required consent of Public Company pursuant to Section 5.1 (other than clause (A) of paragraph (j) or paragraphs (k) or (l) thereof) had such action or event occurred after the date of this Agreement.

3.8 Taxes.

(a) Each of Otic Pharma and its Subsidiaries has properly filed on a timely basis all income and other material Tax Returns that it was required to file, and all such Tax Returns were true, correct and complete in all material respects. Each of Otic Pharma and its Subsidiaries has paid on a timely basis all Taxes that were due and payable. The unpaid Taxes of Otic Pharma and each of its Subsidiaries for Tax periods through the date of the Otic Pharma Balance Sheet do not exceed the accruals and reserves for Taxes (excluding accruals and reserves for deferred Taxes established to reflect timing differences between book and Tax income) set forth on the Otic Pharma Balance Sheet and all unpaid Taxes of Otic Pharma and each of its Subsidiaries for all Tax periods

[Table of Contents](#)

commencing after the date of the Otic Pharma Balance Sheet arose in the Ordinary Course of Business. Neither Otic Pharma nor any of its Subsidiaries is or has ever been a member of an affiliated group with which it has filed (or been required to file) consolidated, combined, unitary or similar Tax Returns, other than a group of which the common parent is Otic Pharma. With the exception of customary commercial leases or contracts that are not primarily related to Taxes entered into in the Ordinary Course of Business and liabilities thereunder, neither Otic Pharma nor any of its Subsidiaries (i) has any actual or potential liability under Treasury Regulations Section 1.1502-6 (or any comparable or similar provision of federal, state, local or foreign law), as a transferee or successor, pursuant to any contractual obligation, or otherwise for any Taxes of any person other than Otic Pharma or any of its Subsidiaries, or (ii) is a party to or bound by any Tax indemnity, Tax sharing, Tax allocation or similar agreement. All material Taxes that Otic Pharma or any of its Subsidiaries was required by law to withhold or collect have been duly withheld or collected and, to the extent required, have been properly paid to the appropriate Governmental Entity, and each of Otic Pharma and its Subsidiaries has complied with all material information reporting and backup withholding requirements, including the maintenance of required records with respect thereto, in connection with amounts paid to any employee, independent contractor, creditor, or other third party. For purposes of this Agreement, (i) “Taxes” shall mean any and all taxes, charges, fees, duties, contributions, levies or other similar assessments or liabilities in the nature of a tax, including, without limitation, income, gross receipts, corporation, ad valorem, premium, value-added, net worth, capital stock, capital gains, documentary, recapture, alternative or add-on minimum, disability, estimated, registration, recording, excise, real property, personal property, sales, use, license, lease, service, service use, transfer, withholding, employment, unemployment, insurance, social security, national insurance, health tax, business license, business organization, environmental, workers compensation, payroll, profits, severance, stamp, occupation, windfall profits, customs duties, franchise and other taxes of any kind whatsoever imposed by the United States of America or any state, local or foreign government, or any agency or political subdivision thereof, and any interest, fines, penalties, assessments or additions to tax imposed with respect to such items, and (ii) “Tax Returns” shall mean any and all reports, returns (including information returns), declarations, or statements relating to Taxes, including any schedule or attachment thereto and any amendment thereof, filed with or submitted to a Governmental Entity in connection with the determination, assessment, collection or payment of Taxes or in connection with the administration, implementation or enforcement of or compliance with any legal requirement relating to any Tax.

(b) Otic Pharma has delivered or made available to Public Company (i) complete and correct copies of all Tax Returns of Otic Pharma and any of its Subsidiaries relating to Taxes for all taxable periods for which the applicable statute of limitations has not yet expired, (ii) complete and correct copies of all private letter rulings, revenue agent reports, information document requests, notices of proposed deficiencies, deficiency notices, protests, petitions, closing agreements, settlement agreements, pending ruling requests and any similar documents submitted by, received by, or agreed to by or on behalf of Otic Pharma or any of its Subsidiaries relating to Taxes for all taxable periods for which the statute of limitations has not yet expired, and (iii) complete and correct copies of all material agreements, rulings, settlements or other Tax documents with or from any Governmental Entity relating to Tax incentives of Otic Pharma or any of its Subsidiaries. No examination or audit of any Tax Return of Otic Pharma or any of its Subsidiaries by any Governmental Entity is currently in progress or, to the knowledge of Otic Pharma, threatened or contemplated. Neither Otic Pharma nor any of its Subsidiaries has been informed in writing by any jurisdiction in which Otic Pharma or any Subsidiary does not file a Tax Return that the jurisdiction believes that Otic Pharma or any of its Subsidiaries was required to file any Tax Return that was not filed or is subject to Tax in such jurisdiction. Neither Otic Pharma nor any of its Subsidiaries has (i) waived any statute of limitations with respect to Taxes or agreed to extend the period for assessment or collection of any Taxes, which waiver or extension is still in effect, (ii) requested any extension of time within which to file any Tax Return, other than routine extensions available as a matter of right which Tax Return has not yet been filed, or (iii) executed or filed any power of attorney with any taxing authority, which is still in effect.

(c) Neither Otic Pharma nor any of its Subsidiaries has made any payment, is obligated to make any payment, or is a party to any agreement that could obligate it to make any payment that may be treated as an “excess parachute payment” under Section 280G of the Code (without regard to Sections 280G(b)(4) and 280G(b)(5) of the Code).

[Table of Contents](#)

(d) Neither Otic Pharma nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(e) Neither Otic Pharma nor any of its Subsidiaries has distributed to its shareholders or security holders stock or securities of a controlled corporation, nor has stock or securities of Otic Pharma or any of its Subsidiaries been distributed, in a transaction to which Section 355 of the Code applies (i) in the two years prior to the date of this Agreement or (ii) in a distribution that could otherwise constitute part of a “plan” or “series of related transactions” (within the meaning of Section 355(e) of the Code) that includes the transactions contemplated by this Agreement.

(f) There are no Liens with respect to Taxes upon any of the assets or properties of Otic Pharma or any of its Subsidiaries, other than with respect to Taxes not yet due and payable.

(g) Neither Otic Pharma nor any of its Subsidiaries will be required to include any item of income in, or exclude any item of deduction from, taxable income for any period (or any portion thereof) ending after the Closing Date as a result of any (i) adjustments under Section 481 of the Code (or any similar adjustments under any provision of the Code or the corresponding foreign, state or local Tax laws), (ii) deferred intercompany gain or any excess loss account described in Treasury Regulations under Section 1502 of the Code (or any corresponding provision of state, local or foreign Tax law), (iii) closing agreement as described in Section 7121 of the Code (or any corresponding or similar provision of state, local or foreign Tax law) executed on or prior to the Closing Date, (iv) installment sale or other open transaction disposition made on or prior to the Closing Date, (v) prepaid amount received on or prior to the Closing Date, or (vi) any election made pursuant to Section 108(i) of the Code on or prior to the Closing Date.

(h) Neither Otic Pharma nor any of its Subsidiaries has participated in any “reportable transaction” as defined in section 1.6011-4(b) of the Treasury Regulations or any analogous provision of state or local law.

(i) Neither Otic Pharma nor any Subsidiary (i) is a party to any joint venture, partnership, or other arrangement that is treated as a partnership for federal income Tax purposes, (ii) has made an entity classification (“check-the-box”) election under Section 7701 of the Code, (iii) is, or has been, a shareholder of a “controlled foreign corporation” as defined in Section 957 of the Code (or any similar provision of state, local or foreign law), or (iv) is, or has been, a shareholder in a “passive foreign investment company” within the meaning of Section 1297 of the Code.

(j) Neither Otic Pharma nor any Subsidiary (A) has or has had a permanent establishment in any country (other than its country of incorporation) as defined in any applicable Tax treaty or convention between such foreign country and Otic Pharma’s or its Subsidiary’s country of incorporation or (B) has or has had operations constituting doing business for Tax purposes in any country (other than its country of incorporation).

(k) The Otic Pharma Share Plan is intended to qualify as a capital gains track plan under Section 102 of the Israeli Income Tax Ordinance (a “102 Plan”), and has received a favorable determination or approval letter from, or is otherwise approved by, or deemed approved by passage of time without objection by, the ITA. Otic Pharma Share Capital and Otic Pharma Share Options which are subject to Tax under Section 102 of the Israeli Income Tax Ordinance and which were issued under any 102 Plan have been granted and issued, as applicable, in compliance with the applicable requirements of Section 102 of the Israeli Income Tax Ordinance (including the relevant sub-sections of Section 102) and the written requirements and guidance of the ITA, including the filing of the necessary documents with the ITA, the appointment of an authorized trustee to hold the Otic Pharma Share Capital and Otic Pharma Share Options, and the due deposit of such Otic Pharma Share Capital and Otic Pharma Share Options with such trustee pursuant to the terms of Section 102 of the Israeli Income Tax Ordinance and the guidance published by the ITA on July 24, 2012 and clarification dated November 6, 2012.

[Table of Contents](#)

(l) All related party transactions involving Otic Pharma or any of its Subsidiaries have been conducted at arm's length in compliance with Section 482 of the Code and the Treasury Regulations promulgated thereunder and any comparable provisions of any other Tax law. Each of Otic Pharma and its Subsidiaries has maintained documentation (including any applicable transfer pricing studies) in connection with such related party transactions in accordance with Sections 482 and 6662 of the Code and the Treasury Regulations promulgated thereunder or the comparable provisions of any other foreign Tax law, as applicable, including Section 85A of the Israeli Income Tax Ordinance and the regulations promulgated thereunder.

(m) Otic Pharma and its Subsidiaries have complied in all material respects with all applicable laws relating to the payment and withholding of Taxes, including from payments made or deemed made to employees, suppliers, lenders and other third parties, from payments made or deemed made to any Person and have duly and timely withheld and paid over to the appropriate taxing authority all amounts required to be so withheld and paid under all applicable laws. Otic Pharma and its Subsidiaries are materially in compliance with, and its records contain all information and documents necessary to comply with, all applicable information reporting and withholding requirements under all applicable Tax laws.

(n) Otic Pharma is duly registered for the purposes of Israeli value added tax and has complied in all material respects with the requirements concerning value added Taxes ("VAT"). Otic Pharma (i) has not made any exempt transactions (as defined in the Israel Value Added Tax Law of 1975) and, to the knowledge of Otic Pharma, there are no circumstances by reason of which there might not be an entitlement to full credit of all VAT chargeable or paid on inputs, supplies, and other transactions and imports made by it, (ii) has collected and timely remitted to the relevant taxing authority the output VAT which it is required to collect and remit under any applicable law; and (iii) has not received a refund for input VAT for which it is not entitled under applicable law.

(o) Otic Pharma is not subject to any restrictions or limitations pursuant to Part E2 of the Israeli Income Tax Ordinance or pursuant to any Tax ruling made with reference to the provisions of Part E2 of the Israeli Income Tax Ordinance.

(p) Otic Pharma does not and has never participated or engaged in any transaction listed in Section 131(g) of the Israeli Income Tax Ordinance and the Israeli Income Tax Regulations (Reportable Tax Planning), 5767-2006 promulgated thereunder.

(q) Otic Pharma is not and has never been a real property corporation (*Igud Mekarke'in*) within the meaning of this term under Section 1 of the Israeli Land Taxation Law (Appreciation and Acquisition), 5723-1963.

(r) Each of Otic Pharma and each Subsidiary is a resident for Tax purposes solely in its country of incorporation, and, neither the Company nor its Subsidiary is subject to Tax in any jurisdiction other than its country of incorporation whether by virtue of having employees, or any other place of business in such jurisdiction or by virtue of exercising management and control in such jurisdiction.

(s) Neither Otic Pharma nor any of its Subsidiaries has made a valid election to be treated as a "Privileged Enterprise" (*Mifaal Muadaf*) under the Law for Encouragement of Capital Investments, 1959.

(t) Otic Pharma has provided to Public Company all material documentation relating to any applicable Tax holidays or incentives (other than incentives generally available by operation of law without application to or action by any Governmental Entity). Otic Pharma and its Subsidiaries are in compliance with the requirements of all such Tax holidays and incentives and none of the Tax holidays or incentives will be jeopardized by the consummation of the Transaction.

(u) Otic Pharma does not own any interest in any controlled foreign corporation pursuant to Section 75B of the Israel Income Tax Ordinance, or other entity the income of which is required to be included in the income of Otic Pharma.

[Table of Contents](#)

3.9 Owned and Leased Real Properties.

(a) Neither Otic Pharma nor any of its Subsidiaries owns or has ever owned any real property.

(b) Section 3.9(b) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list of all real property leased, subleased or licensed by Otic Pharma or any of its Subsidiaries as of the date of this Agreement (collectively, the “Otic Pharma Leases”) and the location of the premises. Neither Otic Pharma nor any of its Subsidiaries nor, to the knowledge of Otic Pharma, any other party is in breach or default and no event has occurred, is pending or, to the knowledge of Otic Pharma, is threatened, which, after the giving of notice, with lapse of time, or otherwise, would constitute any such breach or default under any of Otic Pharma Leases, except where the existence of such breaches or defaults, individually or in the aggregate, has not had, and is not reasonably likely to result in, the loss of a material right or in a material liability of Otic Pharma or any of its Subsidiaries. Neither Otic Pharma nor any of its Subsidiaries leases, subleases or licenses any real property to any person other than Otic Pharma and its Subsidiaries. Otic Pharma has made available to Public Company complete and accurate copies of all Otic Pharma Leases.

3.10 Intellectual Property.

(a) To the knowledge of Otic Pharma, Otic Pharma and its Subsidiaries own, license or otherwise possess legally enforceable rights, free and clear of any Liens, to use all material Intellectual Property used or necessary to conduct the business of Otic Pharma and its Subsidiaries as currently conducted, or that would be used or necessary as such business is currently proposed to be conducted (excluding generally commercially available software programs).

(b) The execution and delivery of this Agreement and consummation of the Transaction will not result in the breach of, or create on behalf of any third party the right to terminate or modify, (i) any license, sublicense or other agreement relating to any Intellectual Property owned by Otic Pharma or any of its Subsidiaries that is material to the business of Otic Pharma and its Subsidiaries, taken as a whole, including software that is used in the development or manufacture of or forms a part of any product or service sold by or expected to be sold by Otic Pharma or any of its Subsidiaries, but excluding generally commercially available software programs (such Intellectual Property, the “Otic Pharma Intellectual Property”) or (ii) any license, sublicense and other agreement as to which Otic Pharma or any of its Subsidiaries is a party and pursuant to which Otic Pharma or any of its Subsidiaries is authorized to use any third party Intellectual Property that is material to the business of Otic Pharma and its Subsidiaries, taken as a whole, including software that is used in the development or manufacture of or forms a part of any product or service sold by or expected to be sold by Otic Pharma or any of its Subsidiaries, but excluding generally commercially available software programs (such Intellectual Property, the “Otic Pharma Third Party Intellectual Property”). Section 3.10(b)(i) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list of all Patent Rights and registrations and applications for Trademarks and copyrights included in Otic Pharma Intellectual Property and Section 3.10(b)(ii) sets forth a complete and accurate list of all agreements under which Otic Pharma or any of its Subsidiaries has in-licensed any Otic Pharma Third Party Intellectual Property.

(c) To the knowledge of Otic Pharma, all issued patents and registrations for Trademarks, service marks and copyrights which are owned by or licensed to Otic Pharma or any of its Subsidiaries and that are material to the business of Otic Pharma and its Subsidiaries, taken as a whole, are valid and subsisting and all payments due and all registration and renewal formalities relating to Otic Pharma Intellectual Property are up to date, complete and correct. Otic Pharma and its Subsidiaries have taken reasonable measures to protect the proprietary nature of the Otic Pharma Intellectual Property. To the knowledge of Otic Pharma, as of the date of this Agreement (i) no other person or entity is infringing, violating or misappropriating any of the Otic Pharma Intellectual Property or Otic Pharma Third Party Intellectual Property and (ii) no claim or demand has been made in writing and no proceeding has been filed or is threatened in writing asserting that such Intellectual Property is invalid or unenforceable.

[Table of Contents](#)

(d) To the knowledge of Otic Pharma, none of the (i) products previously or currently sold by Otic Pharma or any of its Subsidiaries or (ii) business or activities previously or currently conducted by Otic Pharma or any of its Subsidiaries infringes, violates or constitutes a misappropriation of any Intellectual Property of any third party. As of the date of this Agreement, neither Otic Pharma nor any of its Subsidiaries has received any written complaint, claim or notice alleging any such infringement, violation or misappropriation.

(e) For purposes of this Agreement, the following terms shall have the following meanings:

(i) “Intellectual Property” means the following subsisting throughout the world:

(A) Patent Rights;

(B) Trademarks and all goodwill in the Trademarks;

(C) copyrights, designs, data and database rights and registrations and applications for registration thereof, including moral rights of authors;

(D) mask works and registrations and applications for registration thereof under the laws of any jurisdiction;

(E) inventions, invention disclosures, statutory invention registrations, trade secrets and confidential business information, know-how, manufacturing and product processes and techniques, research and development information, financial, marketing and business data, pricing and cost information, business and marketing plans and customer and supplier lists and information, whether patentable or nonpatentable, whether copyrightable or non-copyrightable and whether or not reduced to practice; and

(F) other proprietary rights relating to any of the foregoing (including remedies against infringement thereof and rights of protection of interest therein under the laws of all jurisdictions).

(ii) “Patent Rights” means all patents, patent applications, utility models, and design registrations (including all related continuations, continuations-in-part, divisionals, reissues and reexaminations).

(iii) “Trademarks” means all registered trademarks and service marks, logos, Internet domain names, corporate names and doing business designations and all registrations and applications for registration of the foregoing, common law trademarks and service marks and trade dress.

3.11 Contracts.

(a) As of the date of this Agreement, there are no Contracts that are material contracts (as defined in Item 601(b)(10) of Regulation S-K) with respect to Otic Pharma (assuming Otic Pharma was subject to the requirements of the Exchange Act), other than those Contracts identified in Section 3.11(a) of the Otic Pharma Disclosure Schedule.

(b) Neither Otic Pharma nor any of its Subsidiaries has entered into any transaction that would be subject to proxy statement disclosure pursuant to Item 404 of Regulation S-K (assuming Otic Pharma was subject to the requirements of the Exchange Act), other than as disclosed in Section 3.11(b) of the Otic Pharma Disclosure Schedule.

(c) Neither Otic Pharma nor any of its Subsidiaries is a party to any agreement under which a third party would be entitled to receive a license or any other right to Otic Pharma Intellectual Property as a result of the transactions contemplated by this Agreement.

[Table of Contents](#)

(d) Section 3.11(d) of the Otic Pharma Disclosure Schedule lists the following Contracts of Otic Pharma in effect as of the date of this Agreement:

(i) any Contract (or group of related Contracts) for the purchase or sale of products or for the furnishing or receipt of services (A) which calls for performance over a period of more than 180 days from the date of this Agreement, (B) which involves an aggregate of more than \$150,000 or (C) in which Otic Pharma or any of its Subsidiaries has granted manufacturing rights, “most favored nation” pricing provisions or marketing or distribution rights relating to any products or territory or has agreed to purchase a minimum quantity of goods or services or has agreed to purchase goods or services exclusively from a particular party;

(ii) any Contract under which the consequences of a default or termination would reasonably be likely to have a Otic Pharma Material Adverse Effect;

(iii) any Contract that could reasonably be expected to have the effect of prohibiting or impairing the conduct of the business of Otic Pharma or any of its Subsidiaries or Public Company or any of its Subsidiaries as currently conducted and as currently proposed to be conducted;

(iv) any Contract under which Otic Pharma or any of its Subsidiaries is restricted from selling, licensing or otherwise distributing any of its technology or products, or providing services to, customers or potential customers or any class of customers, in any geographic area, during any period of time or any segment of the market or line of business;

(v) any dealer, distribution, joint marketing, joint venture, joint development, partnership, strategic alliance, collaboration, development agreement or outsourcing arrangement;

(vi) any Contract for the conduct of research studies, pre-clinical or clinical studies, manufacturing, distribution, supply, marketing or co-promotion of any products in development by or which has been or which is being marketed, distributed, supported, sold or licensed out, in each case by or on behalf of Otic Pharma or any of its Subsidiaries; and

(vii) any Contract that would entitle any third party to receive a license or any other right to intellectual property of Public Company or any of Public Company’s Affiliates following the Closing.

(e) Otic Pharma has made available to Public Company a complete and accurate copy of each Contract listed in Sections 3.10(b)(i), 3.10(b)(ii), 3.11(a), 3.11(b) and 3.11(d) of the Otic Pharma Disclosure Schedule. With respect to each Contract so listed: (i) the Contract is legal, valid, binding and enforceable and in full force and effect against Otic Pharma and/or its Subsidiaries party thereto, as applicable, and, to the knowledge of Otic Pharma, against each other party thereto, as applicable, subject to the Bankruptcy and Equity Exception; (ii) the Contract will continue to be legal, valid, binding and enforceable and in full force and effect against Otic Pharma and/or its Subsidiaries party thereto, as applicable, and, to the knowledge of Otic Pharma, against each other party thereto, immediately following the Closing in accordance with the terms thereof as in effect immediately prior to the Closing (other than any such Contracts that expire or terminate before such time in accordance with their terms and not as a result of a breach or default by Otic Pharma or its Subsidiaries), in each such case subject to the Bankruptcy and Equity Exception; and (iii) none of Otic Pharma, its Subsidiaries nor, to the knowledge of Otic Pharma, any other party, is in breach or violation of, or default under, any such Contract, and no event has occurred, is pending or, to the knowledge of Otic Pharma, is threatened, which, with or without notice or lapse of time, or both, would constitute a breach or default by Otic Pharma, its Subsidiaries or, to the knowledge of Otic Pharma, any other party under such Contract, except for such breaches, violations or defaults that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect.

(f) For purposes of this Agreement, the term “Contract” shall mean, with respect to any person, any written, oral or other agreement, contract, subcontract, lease (whether for real or personal property), mortgage,

[Table of Contents](#)

understanding, arrangement, instrument, note, option, warranty, license, sublicense, insurance policy, benefit plan or commitment or undertaking of any nature to which such person is a party or by which such person or any of its assets are bound under applicable law.

3.12 Litigation. There is no action, suit, proceeding, claim, arbitration or investigation before any Governmental Entity or before any arbitrator that is pending or threatened in writing against Otic Pharma or any of its Subsidiaries that (a) seeks either damages in excess of \$100,000 or equitable relief or (b) in any manner challenges or seeks to prevent, enjoin, alter or delay the transactions contemplated by this Agreement, except for such actions, suits, proceedings, claims, arbitrations or investigations first arising after the date of this Agreement that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect. There are no material judgments, orders or decrees outstanding against Otic Pharma or any of its Subsidiaries.

3.13 Environmental Matters.

(a) Except for such matters that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Otic Pharma Material Adverse Effect:

(i) Otic Pharma and its Subsidiaries have complied with all applicable Environmental Laws;

(ii) the properties currently owned, leased or operated by Otic Pharma and its Subsidiaries (including soils, groundwater, surface water, buildings or other structures) are not contaminated with any Hazardous Substances;

(iii) the properties formerly owned, leased or operated by Otic Pharma or any of its Subsidiaries were not contaminated with Hazardous Substances during the period of ownership, use or operation by Otic Pharma or any of its Subsidiaries;

(iv) neither Otic Pharma nor any of its Subsidiaries are subject to liability for any Hazardous Substance disposal or contamination on the property of any third party; and

(v) neither Otic Pharma nor any of its Subsidiaries have released any Hazardous Substance into the environment.

(b) As of the date of this Agreement, neither Otic Pharma nor any of its Subsidiaries has received any written notice, demand, letter, claim or request for information alleging that Otic Pharma or any of its Subsidiaries may be in violation of, liable under or have obligations under, any Environmental Law.

(c) Neither Otic Pharma nor any of its Subsidiaries is subject to any orders, decrees, injunctions or other arrangements with any Governmental Entity or is subject to any indemnity or other agreement with any third party relating to liability under any Environmental Law or relating to Hazardous Substances.

(d) For purposes of this Agreement, the term "Environmental Law" means any law, regulation, order, decree, permit, authorization, opinion, common law or agency requirement of any jurisdiction relating to: (i) the protection, investigation or restoration of the environment, human health and safety or natural resources, (ii) the handling, use, storage, treatment, presence, disposal, release or threatened release of any Hazardous Substance or (iii) noise, odor, wetlands, pollution, contamination or any injury or threat of injury to persons or property.

(e) For purposes of this Agreement, the term "Hazardous Substance" means any substance that is: (i) listed, classified, regulated or which falls within the definition of a "hazardous substance," "hazardous waste" or "hazardous material" pursuant to any Environmental Law; (ii) any petroleum product or by-product, asbestos-

[Table of Contents](#)

containing material, lead-containing paint or plumbing, polychlorinated biphenyls, radioactive materials or radon; or (iii) any other substance that is the subject of regulatory action by any Governmental Entity pursuant to any Environmental Law.

3.14 Employee Benefit Plans.

(a) Section 3.14(a) of the Otic Pharma Disclosure Schedule sets forth a complete and accurate list of all Employee Benefit Plans maintained, or contributed to, by Otic Pharma or any of its Subsidiaries or any of their respective ERISA Affiliates for the benefit of, or relating to, any current or former employee or other service provider of Otic Pharma or any of its Subsidiaries (collectively, the "Otic Pharma Employee Plans"). Except as set forth in Section 3.14(a) of the Otic Pharma Disclosure Schedule, no Otic Pharma Employee Plan is subject to ERISA or covers any person providing services in the United States.

(b) With respect to each Otic Pharma Employee Plan, Otic Pharma has made available to Public Company, a complete and accurate copy of (i) such plan (or a written summary of any unwritten plan), (ii) each trust agreement, group annuity contract and summary plan description, if any, relating to such Otic Pharma Employee Plan, (iii) the three (3) most recent financial statements for each Otic Pharma Employee Plan that is funded, (iv) all personnel, payroll and employment manuals and policies, (v) all employee handbooks, (vi) all regulatory or other filings or submissions to any Governmental Entity with respect to each Otic Pharma Employee Plan, if any, (vii) all material correspondence to or from any Governmental Entity received in the last three years with respect to each Otic Pharma Employee Plan, if any.

(c) Each Otic Pharma Employee Plan has been administered in all respects in accordance with applicable laws and the regulations thereunder and in accordance with its terms and each of Otic Pharma and its Subsidiaries and their respective ERISA Affiliates has in all respects met its obligations with respect to such Otic Pharma Employee Plan and has made all required contributions thereto (or reserved such contributions on the Otic Pharma Balance Sheet). Otic Pharma and its Subsidiaries and each of their respective ERISA Affiliates and each Otic Pharma Employee Plan are in compliance in all respects with the currently applicable law. All filings and reports as to each Otic Pharma Employee Plan required to have been submitted under applicable law have been timely submitted. There is no audit, investigation or other proceeding (including any voluntary correction application) pending against or involving any Otic Pharma Employee Plan. There have been no events with respect to any Otic Pharma Employee Plan that could result in payment or assessment by or against Otic Pharma or any of its Subsidiaries of any Taxes. With respect to Otic Pharma Employee Plans, no event has occurred, and to the knowledge of Otic Pharma, there exists no condition or set of circumstances in connection with which Otic Pharma or any of its Subsidiaries could be subject to any liability that is reasonably likely, individually or in the aggregate, to have a Otic Pharma Material Adverse Effect under applicable law.

(d) There are no legal proceedings (except claims for benefits payable in the normal operation of the Otic Pharma Employee Plan) against or involving any Otic Pharma Employee Plan or asserting any rights or claims to benefits under any Otic Pharma Employee Plan. Neither Otic Pharma nor any of its Subsidiaries has received any written notice of any audit or examination of any Otic Pharma Employee Plan by any Governmental Entity.

(e) With respect to Otic Pharma Employee Plans, there are no benefit obligations for which contributions have not been made or properly accrued and there are no benefit obligations that have not been accounted for by reserves, or otherwise properly footnoted in accordance with GAAP, on the financial statements of Otic Pharma, which obligations are reasonably likely, individually or in the aggregate, to have a Otic Pharma Material Adverse Effect. The assets of each Otic Pharma Employee Plan that is funded are reported at their fair market value on the books and records of such Otic Pharma Employee Plan.

(f) All Otic Pharma Employee Plans (if any) that are intended to be qualified under Section 401(a) of the Code have received determination letters from the Internal Revenue Service (the "IRS") to the effect that such Otic Pharma Employee Plans are qualified and the plans and trusts related thereto are exempt from federal

[Table of Contents](#)

income taxes under Sections 401(a) and 501(a), respectively, of the Code, no such determination letter has been revoked and revocation has not been threatened, and no such Otic Pharma Employee Plan has been amended or operated since the date of its most recent determination letter or application therefor in any respect, and no act or omission has occurred, that would adversely affect its qualification or materially increase its cost. Each Otic Pharma Employee Plan that is required to satisfy Section 401(k)(3) or Section 401(m)(2) of the Code has been tested for compliance with, and satisfies the requirements of, Section 401(k)(3) and Section 401(m)(2) of the Code, as the case may be, for each plan year ending prior to the Closing Date.

(g) Neither Otic Pharma nor any of its Subsidiaries nor any of their respective ERISA Affiliates has (i) ever maintained an Employee Benefit Plan that was ever subject to Section 412 of the Code or Title IV of ERISA or (ii) ever been obligated to contribute to a “multiemployer plan” (as defined in Section 4001(a)(3) of ERISA). No Otic Pharma Employee Plan is funded by, associated with or related to a “voluntary employees’ beneficiary association” within the meaning of Section 501(c)(9) of the Code. No Otic Pharma Employee Plan holds securities issued by Otic Pharma or any of its Subsidiaries or any of their respective ERISA Affiliates.

(h) Each Otic Pharma Employee Plan is amendable and terminable unilaterally by Otic Pharma and any of Otic Pharma’s Subsidiaries and their respective ERISA Affiliates that are a party thereto or covered thereby at any time without liability to Otic Pharma or any of its Subsidiaries or their respective ERISA Affiliates as a result thereof (other than for benefits accrued through the date of termination or amendment and reasonable administrative expenses related thereto), and no Otic Pharma Employee Plan, plan documentation or agreement, summary plan description or other written communication distributed generally to employees by its terms prohibits Otic Pharma or any of its Subsidiaries or their respective ERISA Affiliates from amending or terminating any such Otic Pharma Employee Plan. The investment vehicles used to fund Otic Pharma Employee Plans may be changed at any time without incurring a sales charge, surrender fee or other similar expense.

(i) Neither Otic Pharma nor any of its Subsidiaries nor any of their respective ERISA Affiliates is a party to any oral or written (i) agreement with any shareholders, director, executive officer or other key employee of Otic Pharma or any of its Subsidiaries (A) the benefits of which are contingent, or the terms of which are altered, upon the occurrence of a transaction involving Otic Pharma or any of its Subsidiaries of the nature of any of the transactions contemplated by this Agreement, (B) providing any term of employment or compensation guarantee or (C) providing severance benefits or other benefits after the termination of employment of such director, executive officer or key employee; (ii) agreement, plan or arrangement under which any person may receive payments from Otic Pharma or any of its Subsidiaries or any of its ERISA Affiliates that may be subject to the tax imposed by Section 4999 of the Code or included in the determination of such person’s “parachute payment” under Section 280G of the Code, without regard to Section 280G(b)(4) of the Code; (iii) agreement providing any person providing for “tax gross up” or tax indemnifications related to Sections 280G or 409A of the Code or otherwise; or (iv) agreement or plan binding Otic Pharma or any of its Subsidiaries or any of its ERISA Affiliates, including any stock option plan, stock appreciation right plan, restricted stock plan, stock purchase plan or severance benefit plan, any of the benefits of which shall be increased, or the vesting of the benefits of which shall be accelerated, by the occurrence of any of the transactions contemplated by this Agreement or the value of any of the benefits of which shall be calculated on the basis of any of the transactions contemplated by this Agreement. There are no loans or extensions of credit by Otic Pharma, any of its Subsidiaries or any of their respective ERISA Affiliate to any employee or any other service provider to Otic Pharma or any of its Subsidiaries.

(j) None of the Otic Pharma Employee Plans promises or provides post-termination medical or other post-termination welfare benefits to any person, except as required by applicable law and at the sole expense of the participant

(k) Otic Pharma and its Subsidiaries are in material compliance with all applicable provisions of the Affordable Care Act, including reporting requirements, and there has been no change in health plan terms or coverage that would reasonably be expected to attract an excise tax under Section 4980H of the Code for the current year.

[Table of Contents](#)

(l) Each Otic Pharma Employee Plan that is a “nonqualified deferred compensation plan” (as defined in Section 409A(d)(1) of the Code) complies in form and operation with Section 409A of the Code and all IRS regulations and other guidance promulgated thereunder. No event has occurred that would be treated by Section 409A(b) of the Code as a transfer of property for purposes of Section 83 of the Code. No stock option or equity unit option granted under any Otic Pharma Employee Plan has an exercise price that has been or may be less than the fair market value of the underlying stock or equity units (as the case may be) as of the date such option was granted or has any feature for the deferral of compensation other than the deferral of recognition of income until the later of exercise or disposition of such option. No nonqualified deferred compensation plan has been administered in a manner that would cause an excise tax to apply to payments to plan participants.

(m) Section 3.14(m) of the Otic Pharma Disclosure Schedule sets forth the policy of Otic Pharma and each of its Subsidiaries with respect to accrued vacation, accrued sick time and earned time off and the amount of such liabilities as of September 30, 2016.

(n) For purposes of this Agreement, the following terms shall have the following meanings:

(i) “Employee Benefit Plan” means any “employee pension benefit plan” (including as defined in Section 3(2) of ERISA), any “employee welfare benefit plan” (as defined in Section 3(1) of ERISA) and any other written or oral plan, agreement or arrangement involving direct or indirect compensation, including insurance coverage, severance benefits, disability benefits, fringe benefits, perquisites, change in control benefits, deferred compensation, bonuses, stock options, stock purchase, phantom stock, stock appreciation or other forms of incentive compensation or post-retirement compensation and all unexpired severance agreements, written or otherwise.

3.15 Compliance With Laws. Otic Pharma and each of its Subsidiaries has complied in all material respects with, is not in material violation of, and, as of the date of this Agreement, has not received any notice alleging any material violation with respect to, any applicable provisions of any statute, law or regulation with respect to the conduct of its business, or the ownership or operation of its properties or assets.

3.16 Permits and Regulatory Matters.

(a) Otic Pharma and each of its Subsidiaries have all permits, licenses, registrations, authorizations, certificates, orders, approvals, franchises, variances and other similar rights issued by or obtained from any Governmental Entities (collectively, “Permits”) that are material to the conduct of its business as currently conducted, including a business permit and all such Permits required by the U.S. Food and Drug Administration (the “FDA”) and any other federal, state or foreign agencies or bodies (together with the FDA, the “Regulating Authority”) engaged in the regulation of pharmaceuticals or biohazardous materials.

(b) All Permits that are necessary for the conduct of the business of Otic Pharma and each of its Subsidiaries as currently conducted (“Otic Pharma Authorizations”) are in full force and effect, and to the knowledge of Otic Pharma, no violations or notices of failure to comply have been issued or recorded in respect of any such Otic Pharma Authorization. No such Otic Pharma Authorization shall cease to be effective as a result of the consummation of the transactions contemplated by this Agreement. Otic Pharma and each of its Subsidiaries is in compliance in all material respects under any of such Otic Pharma Authorizations. All applications, reports, notices and other documents required to be filed by Otic Pharma and its Subsidiaries with all Governmental Entities under the Otic Pharma Authorizations have been timely filed and are complete and correct in all material respects as filed or as amended prior to the date of this Agreement. None of Otic Pharma, any Subsidiary of Otic Pharma, and to Otic Pharma’s knowledge, any officer, employee or agent of Otic Pharma or any of its Subsidiaries has been convicted of any crime or engaged in any conduct that has previously caused or would reasonably be expected to result in (A) disqualification or debarment by the FDA under 21 U.S.C. Sections 335(a) or (b), or any similar law, rule or regulation of any other Governmental Entity, or (B) exclusion under 42 U.S.C. Section 1320a-7 or any similar law, rule or regulation of any Governmental Entity.

Table of Contents

(c) Otic Pharma and each of its Subsidiaries: (i) is and at all times has been in material compliance, to the extent applicable, with all statutes, rules, regulations, and with all orders and guidance administered or issued by the FDA or any other Governmental Entity exercising comparable authority, applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product tested, developed, promoted, marketed, manufactured or distributed by Otic Pharma and each of its Subsidiaries; (ii) has not received any notice or correspondence from any Governmental Entity alleging or asserting any noncompliance with any Otic Pharma Authorizations; and (iii) has not received notice that any Governmental Entity has taken or is intending to take action to limit, suspend, modify or revoke any Otic Pharma Authorizations and, to the knowledge of Otic Pharma, there is no action or proceeding pending or threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case alleging that such Governmental Entity is considering such action. Neither Otic Pharma nor any of its Subsidiaries nor any of their respective officers, employees or agents have made an untrue statement of a material fact or fraudulent statement to any Governmental Entity relating to the Otic Pharma Authorizations or failed to disclose a material fact required to be disclosed to any Governmental Entity relating to the Otic Pharma Authorizations.

(d) There are no seizures, recalls, market withdrawals, field notifications or corrective actions, notifications of misbranding or adulteration, destruction orders, safety alerts or similar actions relating to the safety or efficacy of any products marketed or sold by Otic Pharma or any of its Subsidiaries being conducted, requested in writing or, to the knowledge of Otic Pharma, threatened by the FDA or any other Governmental Entity. Otic Pharma has not, either voluntarily or involuntarily, initiated, conducted or issued or caused to be initiated, conducted or issued any recall, market withdrawal, safety alert or other similar notice or action relating to the alleged lack of safety or efficacy of any products marketed or sold by Otic Pharma or any of its Subsidiaries.

(e) The studies, tests and preclinical and clinical trials, if any, conducted by or on behalf of Otic Pharma or any of its Subsidiaries are being conducted or have been conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional and scientific standards for products or product candidates comparable to those being developed by Otic Pharma or its Subsidiaries and all applicable laws and regulations. The descriptions of, protocols for, and data and other results of, any such studies, tests and/or trials that have been furnished or made available to Public Company are accurate and complete in all material respects. Otic Pharma is not aware of any studies, test or trials the results of which reasonably call into question the results of the studies, tests and trials conducted by or on behalf of Otic Pharma or any of its Subsidiaries, and neither Otic Pharma nor any of its Subsidiaries has received any notices or correspondence from the FDA or any other Governmental Entity exercising comparable authority or any institutional review board or comparable authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of Otic Pharma or any of its Subsidiaries.

3.17 Employees.

(a) All current and past employees, founders and current and former independent contractors of Otic Pharma or any of its Subsidiaries have entered into confidentiality and assignment of inventions agreements (which include a waiver of moral rights) with Otic Pharma or such Subsidiary, a copy or form of which has previously been made available to Public Company. All former and current employees have executed a waiver of the right to claim royalties in Service Inventions as defined in Section 132 of the Israel Patents Law, 1967 (the "Patents Law"). The Intellectual Property owned by Otic Pharma was developed and created solely by either (i) employees of Otic Pharma or its Subsidiaries acting within the scope of their employment or (ii) by third parties who have validly and irrevocably assigned all of their rights therein to Otic Pharma or its Subsidiaries, and no third party owns or has any claim, right or interest in or to any of the Intellectual Property owned by Otic Pharma.

[Table of Contents](#)

(b) To the knowledge of Otic Pharma, no Otic Pharma personnel who was involved in, or who contributed to, the creation or development of any Intellectual Property owned by Otic Pharma, has performed services for any Governmental Entity, university, college or other educational institution or research center with respect to technology or inventions that have been or may be incorporated into a product of Otic Pharma or related to Intellectual Property owned by Otic Pharma, during a period of time during which such Otic Pharma personnel was also performing services for Otic Pharma or any of its Subsidiaries. Otic Pharma and its Subsidiaries are not subject to any order of any Governmental Entity that restricts or impairs the use, transfer or licensing of any portion of Intellectual Property owned by Otic Pharma.

(c) To the knowledge of Otic Pharma, as of the date of this Agreement, no employee of Otic Pharma or any Subsidiary of Otic Pharma is in violation of any term of any patent disclosure agreement, non-competition agreement, or any restrictive covenant to a former employer relating to the right of any such employee to be employed by Otic Pharma or any of its Subsidiaries because of the nature of the business currently conducted by Otic Pharma or any of its Subsidiaries or to the use of trade secrets or proprietary information of others. To the knowledge of Otic Pharma, as of the date of this Agreement, no key employee or group of key employees has any plans to terminate employment with Otic Pharma or its Subsidiaries.

(d) Neither Otic Pharma nor any of its Subsidiaries is a party to or otherwise bound by any collective bargaining agreement, contract or other agreement or understanding with a labor union or labor organization. Neither Otic Pharma nor any of its Subsidiaries is the subject of any proceeding asserting that Otic Pharma or any of its Subsidiaries has committed an unfair labor practice or is seeking to compel it to bargain with any labor union or labor organization, nor is there pending or, to the knowledge of Otic Pharma, threatened, any labor strike, dispute, walkout, work stoppage, slow-down or lockout involving Otic Pharma or any of its Subsidiaries.

(e) Section 3.17(e) of the Otic Pharma Disclosure Schedule contains a list of all employees of Otic Pharma and its Subsidiaries along with the position, the annual rate of salary of each such employee, whether such employee is full time or part time, is exempt or non-exempt from overtime compensation laws, is on leave and if so, the type of leave and expected date of return, visa status (as applicable), date of hire, any incentive payment paid or payable in calendar year 2016 (and whether such incentive is cash or, if not, what other property is due), short-term or temporary basis, vacation entitlement and accrued vacation or paid time-off balance, car entitlement, sick leave entitlement and accrual (if any), and recuperation pay entitlement and accrual, pension entitlements and provident funds (including manager's insurance, pension fund, education fund and health fund), their respective contribution rates for each component (e.g., severance component, pension savings and disability insurance) and the salary basis for such contributions, severance entitlements (including whether such employee, to the extent employed in the State of Israel, is subject to a Section 14 arrangement under the Severance Pay Law, 5723 1963 (the "Israeli Severance Pay Law" and "Section 14 Arrangement")), and, to the extent such employee is subject to such a Section 14 Arrangement, an indication of whether such arrangement (or other applicable pension arrangement) has been applied to such person from the commencement date of their employment and on the basis of their entire salary including other compensation (e.g., commission), main work location, notice period entitlement, and any other material compensation payable to such employee. Neither Otic Pharma nor its Subsidiaries is delinquent in payments to any employees for wages, salaries, commissions or bonuses for services performed as of the date of this Agreement or amounts required by applicable law to be reimbursed to such employees. The consummation of the Transaction will not give rise to any liability of Otic Pharma or any of its Subsidiaries for payments related to severance, termination, bonus, accrued vacation or personal time, accrued days of sick pay or any similar payment.

(f) Otic Pharma and its Subsidiaries are, and at all times within applicable statutes of limitations have been, in material compliance with all applicable laws respecting labor, employment, hiring and termination, fair employment practices, terms and conditions of employment, occupational health and safety and wage and hour laws, including the Advance Notice for Dismissal and Resignation Law, 5761-2001, the Notification to an Employee (Terms of Employment) Law, 5762-2002, the Wage Protection Law 5718-1958, Prior Notice to the Employee Law, 5762-2002, the Prevention of Sexual Harassment Law, 5758-1998, the Hours of Work and Rest

[Table of Contents](#)

Law, 5711-1951, the Annual Leave Law, 5711-1951, the Employment by Human Resource Contractors Law, 5756-1996 and the Increased Enforcement of Labor Laws-2012. During the past three (3) years, each current and former employee of each of Otic Pharma and its Subsidiaries has been properly categorized as exempt or non-exempt from applicable laws pertaining to payment of minimum wage and overtime compensation and has been paid overtime wages to the extent required by applicable law. Each individual who has rendered services to Otic Pharma or any of its Subsidiaries and has been classified as an independent contractor or other non-employee status for any purpose (including for purposes of Taxes and Tax reporting and under Otic Pharma Employee Plans) has been properly so classified. During the past three (3) years, there has not been and there is no pending or, to the knowledge of Otic Pharma, threatened, any material claim, charge, grievance or Legal Proceeding against Otic Pharma or any of its Subsidiaries brought by or on behalf of any current or former applicant, employee, independent contractor, subcontractor, leased employee, volunteer, or temporary employee of Otic Pharma or its Subsidiaries, alleging violation of any applicable employment law, agreement or any other claim arising out of such Person's employment, application for employment or termination of employment, consulting or other relationship with Otic Pharma or any of its Subsidiaries.

(g) Otic Pharma and its Subsidiaries have withheld, paid and reported all amounts required by the Israeli Tax Ordinance, the National Insurance Law (Consolidated Version), 5755 1995, the National Health Insurance Law, 5754-1994 or any other law or by contract to be withheld, paid and reported with respect to compensation, wages, salaries, payments to the National Insurance Institute, employees' pension or managers insurance funds, disability insurance, continuing education fund or other similar funds and other payments to employees or consultants of Otic Pharma and its Subsidiaries. Neither Otic Pharma nor any of its Subsidiaries is required to make payments for overtime hours above the global overtime compensation paid by it.

(h) At all times since January 1, 2014, Otic Pharma and its Subsidiaries have never engaged any employees whose employment would require special licenses or permits by Otic Pharma or its Subsidiaries. Otic Pharma and its Subsidiaries have not engaged, and do not currently engage, any contractors or contractors' employees who, according to Israeli law, would reasonably be expected to be entitled to the rights of an employee vis-à-vis Otic Pharma or its Subsidiaries, including rights to severance pay, vacation, recuperation pay (*dmei havraa*) and other employee-related statutory and contractual benefits.

(i) Otic Pharma's and (if applicable) its Subsidiaries' obligations to provide statutory severance pay to its Israeli employees pursuant to the Israeli Severance Pay Law are fully funded in accordance with Section 14 under the Israeli Severance Pay Law and it is and was implemented properly, from the commencement date of the employee's employment and on the basis of the employee's entire salary. Upon the termination of employment of Israeli employees, Otic Pharma will not have to make any payment under the Israeli Severance Pay Law, except for release of the funds accumulated in accordance with Section 14.

(j) Otic Pharma and its Subsidiaries are not required (under any law, contract or otherwise) to provide benefits or working conditions beyond the minimum benefits and working conditions required by law to be provided pursuant to rules and regulations of the Israeli Histadrut (General Federation of Labor), the Israeli Coordinating Bureau of Economic Organization and the Israeli Industrialists' Association. Otic Pharma and its Subsidiaries have not and are not subject to, and no employee or consultant of them benefits from, any extension order (*tzavei harchave*) or any general contract or arrangement with respect to employment or termination of employment, except those extension orders that apply to all Israeli companies generally, and there are no unwritten Otic Pharma policies or customs which, by extension, could entitle Israeli employees to any benefits in addition to what they are entitled by applicable law, agreement or any written policy.

(k) Section 3.17(k) of the Otic Pharma Disclosure Schedule contains a list of all employees of each of Otic Pharma and its Subsidiaries who are a party to a non-competition agreement with Otic Pharma; copies of such agreements have previously been delivered, or made available, to Public Company. Section 3.17(k) of the Otic Pharma Disclosure Schedule also contains a list of all employees of each of Otic Pharma and its Subsidiaries who are not citizens or lawful permanent residents of the jurisdiction in which they are working, and for each, the basis of his or her employment authorization in such jurisdiction and the expiration of such authorization.

Table of Contents

3.18 Insurance. Otic Pharma and its Subsidiaries maintain insurance policies (the “Otic Pharma Insurance Policies”), including insurance covering directors and officers for securities law and other customary liabilities, with reputable insurance carriers against all risks of a character and in such amounts as are usually insured against by similarly situated companies in the same or similar businesses. Each Otic Pharma Insurance Policy is in full force and effect. None of the Otic Pharma Insurance Policies shall terminate or lapse (or be affected in any other adverse manner) by reason of any of the transactions contemplated by this Agreement. Otic Pharma and each of its Subsidiaries have complied in all material respects with the provisions of each Otic Pharma Insurance Policy under which it is the insured party. No insurer under any Otic Pharma Insurance Policy has cancelled or generally disclaimed liability under any such policy or indicated any intent to do so or not to renew any such policy. All claims under the Otic Pharma Insurance Policies have been filed in a timely fashion.

3.19 No Fairness Opinion. Otic Pharma has not received, and, as of the date hereof, does not intend to obtain, an opinion from any financial advisor, investment banker or other firm or person performing a similar function, with respect to the fairness of the Transaction, including the fairness of the consideration to be received by holders of Otic Pharma Share Capital in connection with the Transaction.

3.20 Brokers; Fees and Expenses. No agent, broker, investment banker, financial advisor or other firm or person is or shall be entitled, as a result of any action, agreement or commitment of Otic Pharma or any of its Affiliates, to any broker’s, finder’s, financial advisor’s or other similar fee or commission in connection with any of the transactions contemplated by this Agreement, except Piper Jaffray & Co (“Piper”) whose fees and expenses shall be paid by Otic Pharma immediately prior to the Closing. Otic Pharma has made available to Public Company a complete and accurate copy of all agreements pursuant to which Piper is entitled to any fees and expenses in connection with any of the transactions contemplated by this Agreement. Otic Pharma is not a party to any agreements with any agent, broker, investment banker, financial advisor or other similar firm or person that have not been made available to Public Company and which grant to such person rights after the Closing, other than agreement that have been made available to the Public Company.

3.21 Certain Business Relationships With Affiliates. Other than as set forth in Section 3.21 of the Otic Pharma Disclosure Schedules, no Affiliate of Otic Pharma or of any of its Subsidiaries (a) owns any property or right, tangible or intangible, which is used in the business of Otic Pharma or any of its Subsidiaries, (b) has any claim or cause of action against Otic Pharma or any of its Subsidiaries or (c) owes any money to, or is owed any money by, Otic Pharma or any of its Subsidiaries. Section 3.21 of the Otic Pharma Disclosure Schedule describes any material Contracts between Otic Pharma and any Affiliate thereof which were entered into or have been in effect at any time since September 30, 2014, other than (i) any employment Contracts, invention assignment agreements and other Contracts entered into in the Ordinary Course of Business relating to employment, or (ii) Contracts relating to stock purchases and awards, stock options and other equity arrangements, in each case relating to compensation.

3.22 Controls and Procedures, Certifications and Other Matters.

(a) Otic Pharma and each of its Subsidiaries maintains accurate books and records reflecting its assets and liabilities and maintains proper and adequate internal control over financial reporting that provide assurance that (i) transactions are executed with management’s authorization, (ii) transactions are recorded as necessary to permit preparation of the consolidated financial statements of Otic Pharma and to maintain accountability for Otic Pharma’s consolidated assets, (iii) access to assets of Otic Pharma and its Subsidiaries is permitted only in accordance with management’s authorization, (iv) the reporting of assets of Otic Pharma and its Subsidiaries is compared with existing assets at regular intervals and (v) accounts, notes and other receivables and inventory were recorded accurately, and proper and adequate procedures are implemented to effect the collection thereof on a current and timely basis.

(b) Otic Pharma maintains disclosure controls and procedures as would be required by Rules 13a-15 or 15d-15 under the Exchange Act if Otic Pharma were registered under Section 12 of the Exchange Act, and

Table of Contents

such controls and procedures are effective to ensure that all material information concerning Otic Pharma and its Subsidiaries is made known on a timely basis to the individuals responsible for the preparation of Otic Pharma's filings with the SEC and other public disclosure documents. Section 3.22(b) of the Otic Pharma Disclosure Schedule lists, and Otic Pharma has made available to Public Company copies of, all written descriptions of, and all policies, manuals and other documents promulgating, such disclosure controls and procedures.

(c) Neither Otic Pharma nor any of its Subsidiaries has extended or maintained credit, arranged for the extension of credit, modified or renewed an extension of credit, in the form of a personal loan or otherwise, to or for any director or executive officer of Otic Pharma. Section 3.22(c) of the Otic Pharma Disclosure Schedule identifies any loan or extension of credit maintained by Otic Pharma to which the second sentence of Section 13(k)(1) of the Exchange Act applies.

(d) Otic Pharma either (i) satisfies the conditions to qualification as a "smaller reporting company" set forth in 17 C.F.R. 229.10(f)(1), or (ii) if shares of Otic Pharma Ordinary Shares were traded on any regulated market or stock exchange, would qualify as a "smaller reporting company," as defined by 17 C.F.R. 229.10(f)(1).

3.23 Books and Records. The minute books and other similar records of Otic Pharma and each of its Subsidiaries contain complete and accurate records of all material actions taken at any meetings of Otic Pharma's or such Subsidiary's shareholders, Board of Directors or any committee thereof and of all written consents executed in lieu of the holding of any such meeting. The books and records of Otic Pharma and each of its Subsidiaries accurately reflect in all material respects the assets, liabilities, business, financial condition and results of operations of Otic Pharma or such Subsidiary and have been maintained in accordance with good business and bookkeeping practices.

3.24 Ownership of Public Company Common Stock. None of Otic Pharma nor any of Otic Pharma's "Affiliates" or "Associates" directly or indirectly "owns," beneficially or otherwise, and at all times during the three-year period prior to the date of this Agreement, none of Otic Pharma's "Affiliates" or "Associates" directly or indirectly has "owned," beneficially or otherwise, any of the outstanding Public Company Common Stock, as those terms are defined in Section 203 of the DGCL.

3.25 Privacy and Data Security.

(a) Otic Pharma and each of its Subsidiaries, the products and all internet websites owned, maintained or operated by or on behalf of Otic Pharma or any of its Subsidiaries (the "Otic Pharma Sites"), and all third parties, solely in connection with their performance of activities on Otic Pharma's or any of Otic Pharma's Subsidiaries' behalf or in connection with their use of Personal Information collected by or on behalf of Otic Pharma or any of its Subsidiaries, comply, and have at all times complied with all applicable data security, and Privacy Laws. Copies of all current internal and public-facing privacy policies of Otic Pharma, if any, that apply to the Otic Pharma Sites and products have been made available to the Public Company, and none of the disclosures in such policies have been in violation of any Privacy Laws. Any consents required under applicable laws for the collection, processing, transfer and other use of Personal Information by Otic Pharma or any of its Subsidiaries for the conduct of the business of Otic Pharma or any of its Subsidiaries have been obtained. There is no complaint to, or any proceeding, or to the knowledge of Otic Pharma, an investigation (formal or informal) or claim or audit currently pending against, Otic Pharma or any of Otic Pharma's Subsidiaries by any Person with respect to Personal Information and, to the knowledge of Otic Pharma, there is no threatened complaint, proceeding, investigation (formal or informal) or claim against Otic Pharma or any of its Subsidiaries with respect thereto. With respect to all Personal Information collected, stored, used, or maintained by or for Otic Pharma or any of its Subsidiaries, Otic Pharma and its Subsidiaries have at all times implemented reasonable security measures aiming to ensure that such Personal Information is protected against loss and against unauthorized access, use, modification and disclosure. To the knowledge of Otic Pharma, there has been no loss, unauthorized access to or other misuse of such Personal Information. All databases owned, controlled, held or used by Otic Pharma or any of its Subsidiaries and required to be registered under applicable

Table of Contents

laws have been properly registered, and the data therein has been used by Otic Pharma or any of its Subsidiaries solely as permitted pursuant to such registrations. The consummation of the contemplated transactions shall not violate Otic Pharma's internal and public-facing privacy policies as they currently exist or any applicable law.

(b) For the purposes of this Agreement:

“Privacy Laws” shall mean all applicable laws regarding the collection, use and protection of Personal Information (including the Protection of Privacy Law 1981 and related regulations, directives and orders of any Governmental Entity of the State of Israel).

“Personal Information” shall mean individually identifiable information from or about an individual, including an individual's: (a) personally identifiable information (e.g., name, address, telephone number, email address, financial account number, government-issued identifier, details of a person's personality, personal status, intimate affairs, state of health, economic status, professional training, opinions or beliefs and any other data used or intended to be used to identify, contact or precisely locate a person), (b) Internet Protocol address or other persistent identifier; and (c) “information” as defined by the Israeli Protection of Privacy Law, 1981 and applicable Israeli judicial precedents defining that term and the corresponding laws of other jurisdictions.

3.26 Government Funding. Otic Pharma is subject to the provisions of the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744 1984, or the “Innovation Law” (formerly known as the Israeli Encouragement of Industrial Research and Development Law 5744-1984), as amended from time to time and/or such other law as will be legislated in lieu thereof, including the regulations, directives, procedures and rules that have been or will be promulgated thereunder and/or by virtue thereof. Section 3.26 of the Otic Pharma Disclosure Schedule provides a true, complete and correct list all pending and outstanding grants, incentives and subsidies from the Government of the State of Israel or any agency thereof, or from any Governmental Entity, granted to Otic Pharma and any of its Subsidiaries, including grants from the OCS (collectively, “Government Grants”). Otic Pharma has made available to Public Company true, complete and correct copies of all documents evidencing Government Grants submitted by Otic Pharma and any its Subsidiaries (or transferred or assigned or purchased by Otic Pharma and any of its Subsidiaries) and of all letters of approval, certificates of completion, and supplements and amendments thereto, granted to Otic Pharma and any of its Subsidiaries, and all material correspondence related thereto. Section 3.26 of the Otic Pharma Disclosure Schedule sets forth: (a) the aggregate amount of each Government Grant; (b) the aggregate outstanding obligations, if any, of Otic Pharma and each of its Subsidiaries under each Government Grant with respect to royalties or other payments; and (c) the outstanding amounts to be paid by the OCS to Otic Pharma and any of its Subsidiaries under the Government Grants, if any. Otic Pharma and each of its Subsidiaries are in compliance with the terms and conditions of all Government Grants and the laws applicable thereto (including the provisions of the Innovation Law and relevant regulations promulgated pursuant thereto), which have been approved, and have duly fulfilled all the undertakings required thereby to be fulfilled. To the knowledge of Otic Pharma, there is no event or other set of circumstances which would reasonably be expected to lead to the revocation or material modification of any of the Government Grants that have been approved. Otic Pharma represents that no OCS funded Intellectual Property is incorporated into Otic Pharma's “Surfactant Platform” products, which are based on intellectual property licensed from Otodyne Inc., and that no OCS funded Intellectual Property is related to Otic Pharma's current and/or anticipated business with respect to the Surfactant Platform. For the purposes of this Agreement “OCS” shall mean the Israel Innovation Authority (formerly known as the Office of the Chief Scientist) of the Israeli Ministry of Economy and Industry.

3.27 Export Control Laws.

(a) Otic Pharma and its Subsidiaries have at all times conducted their export and re-export transactions in accordance with all applicable import/export controls in countries in which Otic Pharma and its Subsidiaries conducts business. Without limiting the foregoing, Otic Pharma and its Subsidiaries have obtained all applicable export and import licenses, approvals and filings with any Governmental Entity required for its

[Table of Contents](#)

export, import and re-export of products, services, software and technologies (“[Export Approvals](#)”). Otic Pharma and its Subsidiaries are in compliance with the terms of all applicable Export Approvals. There are no pending legal proceedings or threatened claims against Otic Pharma and its Subsidiaries with respect to such Export Approvals or export or re-export transactions. There are no actions, conditions or circumstances pertaining to Otic Pharma’s export transactions that would reasonably be expected to give rise to any future claims; and

(b) Otic Pharma’s and its Subsidiaries’ business, as currently conducted, does not involve the use or development of, or engaging in, encryption technology, or other technology whose development, commercialization or export is restricted under Israeli or other applicable foreign law, and Otic Pharma’s and its Subsidiaries’ business, as currently conducted, does not require Otic Pharma or its Subsidiaries to obtain a license from the Israeli Ministry of Defense or an authorized body thereof pursuant to the Control of Products and Services Declaration (Engagement in Encryption), 1974, as amended, or other applicable laws regulating the development, commercialization or export of technology.

3.28 [No Other Representations or Warranties](#). Otic Pharma hereby acknowledges and agrees that, except for the representations and warranties contained in this Agreement, none of Public Company, nor any other person on behalf of Public Company makes any express or implied representation or warranty with respect to Public Company, or with respect to any other information provided to Otic Pharma or any of its Affiliates in connection with the transactions contemplated hereby, and (subject to the express representations and warranties of Public Company set forth in Article IV (in each case as qualified and limited by the Public Company Disclosure Schedule)) none of Otic Pharma or any of its Affiliates, shareholders, directors, officers, employees, agents, representatives or advisors, or any other person, has relied on any such information (including the accuracy or completeness thereof).

ARTICLE IV

REPRESENTATIONS AND WARRANTIES OF PUBLIC COMPANY

Public Company represents and warrants to Otic Pharma that the statements contained in this Article IV are true and correct, except: (a) as disclosed in the Public Company SEC Reports filed or furnished prior to the date of this Agreement, or (b) as expressly set forth herein or in the disclosure schedule delivered by Public Company to Otic Pharma on the date of this Agreement (the “[Public Company Disclosure Schedule](#)”). For purposes hereof, the phrase “to the knowledge of Public Company” and similar expressions mean the actual knowledge of the persons identified on Section K of the Public Company Disclosure Schedule for this purpose, and such knowledge as such persons would reasonably be expected to have obtained in the course of their performance of their positions at the Public Company (but without any special investigation).

4.1 [Organization, Standing and Power](#). Public Company is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction listed on Section 4.1 of the Public Company Disclosure Schedule, which jurisdictions constitute the only jurisdictions in which the character of the properties it owns, operates or leases or the nature of its activities makes such qualification necessary, except for such failures to be so qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect. For purposes of this Agreement, the term “[Public Company Material Adverse Effect](#)” means any material adverse change, effect, event, circumstance or development with respect to, or material adverse effect on, the business, assets, liabilities, capitalization, condition (financial or other), or results of operations of Public Company and its Subsidiaries, taken as a whole; provided, however, that none of the following, to the extent arising after the date of this Agreement, shall be deemed to be a Public Company Material Adverse Effect: any change or event caused by or resulting from (A) changes in prevailing economic or market conditions in the United States or any other jurisdiction in which such entity has substantial business operations (except to the

Table of Contents

extent those changes have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate), (B) changes or events affecting the industry or industries in which Public Company and its Subsidiaries operate generally (except to the extent those changes or events have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate), (C) changes in generally accepted accounting principles or requirements applicable to Public Company and its Subsidiaries (except to the extent those changes have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate), (D) changes in laws, rules or regulations of general applicability or interpretations thereof by any Governmental Entity (except to the extent those changes have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate), (E) any natural disaster or any outbreak of major hostilities in which the United States is involved or any act of terrorism within the United States or directed against its facilities or citizens wherever located (except to the extent those changes or events have a disproportionate effect on Public Company and its Subsidiaries relative to the other participants in the industry or industries in which Public Company and its Subsidiaries operate); (F) a change in the public trading price of Public Company Common Stock or the implications thereof, (G) a change in the trading volume of Public Company Common Stock, (H) any failure by Public Company to meet any public estimates or expectations of Public Company's revenue, earnings or other financial performance or results of operations for any period, or (I) any failure by Public Company to meet any guidance, budgets, plans or forecasts of its revenues, earnings or other financial performance or results of operations (but not, in the case of (F) through (I), the underlying cause of such changes or failures, unless such changes or failures would otherwise be excepted from this definition). For the avoidance of doubt, the parties agree that the terms "material," "materially" and "materiality" as used in this Agreement with an initial lower case "m" shall have their respective customary and ordinary meanings, without regard to the meanings ascribed to Public Company Material Adverse Effect or Otic Pharma Material Adverse Effect, in each case as defined in this Agreement. Public Company has made available to Otic Pharma complete and accurate copies of its certificate of incorporation and bylaws and is not in material default under or in material violation of any provision of any such documents.

4.2 Capitalization.

(a) The authorized capital stock of Public Company consists of 200,000,000 shares of Public Company Common Stock and 5,000,000 shares of preferred stock, \$0.001 par value per share ("Public Company Preferred Stock"). The rights and privileges of each class of Public Company's capital stock are as set forth in Public Company's certificate of incorporation. As of the close of business on the Business Day prior to the date of this Agreement, (i) 22,641,651 shares of Public Company Common Stock were issued or outstanding, (ii) no shares of Public Company Common Stock were held in the treasury of Public Company or by Subsidiaries of Public Company, and (iii) no shares of Public Company Preferred Stock were issued or outstanding.

(b) Section 4.2(b) of the Public Company Disclosure Schedule sets forth a complete and accurate list of the number of shares of Public Company Common Stock reserved for future issuance pursuant to stock options granted and outstanding as of the close of business on the Business Day prior to the date of this Agreement, the plans under which such options were granted (collectively, "Public Company Stock Plans") and the total number of outstanding options to purchase shares of Public Company Common Stock (such outstanding options, "Public Company Stock Options") under the Public Company Stock Plans as of the close of business on the Business Day prior to the date of this Agreement, indicating, as of the date of this Agreement, with respect to each such Public Company Stock Option the name of the holder thereof, the Public Company Stock Plan under which it was granted, the number of shares of Public Company Common Stock subject to such Public Company Stock Option, the exercise price, the date of grant and the vesting schedule, including whether (and to what extent) the vesting will be accelerated in any way by the transactions contemplated by this Agreement or by termination of employment or change in position following consummation of the Transaction, and whether such Public Company Stock Option is intended to be an incentive stock option. As of the close of business on the

Table of Contents

Business Day prior to the date of this Agreement, Public Company has reserved 250,000 shares of Public Company Common Stock for issuance to employees pursuant to Public Company's 2014 Employee Stock Purchase Plan (the "Public Company ESPP"), of which 250,000 shares remain available for issuance thereunder as of the date hereof. Public Company has not granted, issued or authorized the grant or issuance of any Public Company Stock Options on the Business Day prior to the date of this Agreement or on the date of this Agreement. Public Company has made available to Otic Pharma accurate and complete copies of all Public Company Stock Plans and the forms of all stock option agreements evidencing Public Company Stock Options.

(c) Section 4.2(c) of the Public Company Disclosure Schedule lists the number of shares of Public Company Common Stock reserved for future issuance pursuant to warrants or other outstanding rights (other than Public Company Stock Options) to purchase shares of Public Company Common Stock outstanding as of the close of business on the Business Day prior to the date of this Agreement (such outstanding warrants or other rights, the "Public Company Warrants") and the agreement or other document under which such Public Company Warrants were granted, and the exercise price, the date of grant and the expiration date thereof. Public Company has made available to Otic Pharma accurate and complete copies of the forms of agreements evidencing all Public Company Warrants.

(d) Except (i) as set forth in this Section 4.2 or in Article II, (ii) as reserved for future grants under Public Company Stock Plans, outstanding as of the close of business on the Business Day prior to the date of this Agreement and (iii) for the rights to acquire shares pursuant to the Public Company ESPP, (A) there are no equity securities of any class of Public Company, or any security exchangeable into or exercisable for such equity securities, issued, reserved for issuance or outstanding and (B) there are no options, warrants, equity securities, calls, rights, commitments or agreements of any character to which Public Company or any of its Subsidiaries is a party or by which Public Company or any of its Subsidiaries is bound obligating Public Company or any of its Subsidiaries to issue, exchange, transfer, deliver or sell, or cause to be issued, exchanged, transferred, delivered or sold, additional shares of capital stock or other equity interests of Public Company or any security or rights convertible into or exchangeable or exercisable for any such shares or other equity interests, or obligating Public Company or any of its Subsidiaries to grant, extend, accelerate the vesting of, otherwise modify or amend or enter into any such option, warrant, equity security, call, right, commitment or agreement. Public Company does not have any outstanding stock appreciation rights, phantom stock, performance based rights or similar rights or obligations. Other than the Public Company Support Agreement, neither Public Company nor any of its Affiliates is a party to or is bound by any, and to the knowledge of Public Company, there are no, agreements or understandings with respect to the voting (including voting trusts and proxies) or sale or transfer (including agreements imposing transfer restrictions) of any shares of capital stock or other equity interests of Public Company. Except as contemplated by this Agreement or described in this Section 4.2(d), there are no registration rights to which Public Company or any of its Subsidiaries is a party or by which it or they are bound with respect to any equity security of any class of Public Company. Stockholders of Public Company are not entitled to dissenters' or appraisal rights under applicable state law in connection with the Transaction.

(e) All outstanding shares of Public Company Common Stock are, and all shares of Public Company Common Stock subject to issuance as specified in Sections 4.2(b) and 4.2(c) or pursuant to Article II, upon issuance on the terms and conditions specified in the instruments pursuant to which they are issuable, will be, duly authorized, validly issued, fully paid and nonassessable and not subject to or issued in violation of any purchase option, call option, right of first refusal, preemptive right, subscription right or any similar right under any provision of the DGCL, Public Company's certificate of incorporation or bylaws or any agreement to which Public Company is a party or is otherwise bound.

4.3 Subsidiaries.

(a) Section 4.3(a) of the Public Company Disclosure Schedule sets forth, for each Subsidiary of Public Company: (i) its name; (ii) the number and type of outstanding equity securities and a list of the holders thereof; and (iii) the jurisdiction of organization.

[Table of Contents](#)

(b) Each Subsidiary of Public Company is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction where the character of its properties owned, operated or leased or the nature of its activities makes such qualification necessary, except for such failures to be so organized, qualified or in good standing, individually or in the aggregate, that have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect. All of the outstanding shares of capital stock and other equity securities or interests of each Subsidiary of Public Company are duly authorized, validly issued, fully paid, nonassessable and free of preemptive rights and all such shares (other than directors' qualifying shares in the case of non-U.S. Subsidiaries, all of which Public Company has the power to cause to be transferred for no or nominal consideration to Public Company or Public Company's designee) are owned, of record and beneficially, by Public Company or another of its Subsidiaries free and clear of all Liens, claims, pledges, agreements or limitations in Public Company's voting rights. There are no outstanding or authorized options, warrants, rights, agreements or commitments to which Public Company or any of its Subsidiaries is a party or which are binding on any of them providing for the issuance, disposition or acquisition of any capital stock of any Subsidiary of Public Company. There are no outstanding stock appreciation, phantom stock or similar rights with respect to any Subsidiary of Public Company. There are no voting trusts, proxies or other agreements or understandings with respect to the voting of any capital stock of any Subsidiary of Public Company.

(c) Public Company has made available to Otic Pharma complete and accurate copies of the charter, bylaws or other organizational documents of each Subsidiary of Public Company.

(d) Public Company does not control directly or indirectly or have any direct or indirect equity participation or similar interest in any corporation, partnership, limited liability company, joint venture, trust or other business association or entity which is not a Subsidiary of Public Company. There are no obligations, contingent or otherwise, of Public Company or any of its Subsidiaries to repurchase, redeem or otherwise acquire any shares of capital stock of any Subsidiary of Public Company or to provide funds to or make any material investment (in the form of a loan, capital contribution or otherwise) in any Subsidiary of Public Company or any other entity, other than guarantees of bank obligations of Subsidiaries of Public Company entered into in the Ordinary Course of Business.

4.4 Authority; No Conflict; Required Filings and Consents.

(a) Public Company has all requisite corporate power and authority to enter into this Agreement and, subject only to the Public Company Stockholder Approval, to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement by Public Company has been duly authorized by all necessary corporate action on the part of Public Company, subject only to the Public Company Stockholder Approval. This Agreement has been duly executed and delivered by Public Company and constitutes the valid and binding obligation of Public Company, enforceable against Public Company in accordance with its terms, subject to the Bankruptcy and Equity Exception.

(b) The execution and delivery of this Agreement by Public Company does not, and the consummation by Public Company of the Transaction shall not, (i) conflict with, or result in any violation or breach of, any provision of the certificate of incorporation or bylaws of Public Company or of the charter, bylaws or other organizational document of any other Subsidiary of Public Company, (ii) conflict with, or result in any violation or breach of, or constitute (with or without notice or lapse of time, or both) a default (or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any material benefit) under, or require a consent or waiver under, constitute a change in control under, require the payment of a penalty under or result in the imposition of any Lien on Public Company's or any of its Subsidiaries' assets under any of the terms, conditions or provisions of any Contract required to be disclosed in Section 4.11(d) of the Public

Table of Contents

Company Disclosure Schedule, or (iii) subject to obtaining the Public Company Stockholder Approval and compliance with the requirements specified in clauses (i) through (vii) of Section 4.4(c), conflict with or violate any permit, concession, franchise, license, judgment, injunction, order, decree, statute, law, ordinance, rule or regulation applicable to Public Company or any of its Subsidiaries or any of its or their properties or assets, except in the case of clauses (ii) and (iii) of this Section 4.4(b), for any such conflicts, violations, breaches, defaults, terminations, cancellations, accelerations or losses that, individually or in the aggregate have not had, and are not reasonably likely to result in, the loss of a material benefit to, or in the creation of a material liability for, Public Company. Section 4.4(b) of the Public Company Disclosure Schedule lists all consents, waivers and approvals under any of Public Company's or any of its Subsidiaries' agreements, licenses or leases required to be obtained in connection with the consummation of the transactions contemplated by this Agreement, which, if individually or in the aggregate were not obtained, would result in a loss of a material benefit to, or the creation of any material liability for, Public Company or Otic Pharma as a result of the Transaction.

(c) No consent, approval, license, permit, order or authorization of, or registration, declaration, notice or filing with, any Governmental Entity or any stock market or stock exchange on which shares of Public Company Common Stock are listed for trading is required by or with respect to Public Company or any of its Subsidiaries in connection with the execution and delivery of this Agreement or the consummation by Public Company of the transactions contemplated by this Agreement, except for (i) the filing of the Proxy Statement with the SEC in accordance with the Exchange Act, (ii) the filing of such reports, schedules or materials under Section 13 of or Rule 14a-12 under the Exchange Act as may be required in connection with this Agreement and the transactions contemplated hereby and thereby, (iii) such consents, approvals, orders, authorizations, registrations, declarations and filings as may be required under applicable state securities laws and the laws of any foreign country, (iv) a NASDAQ Listing Application—For Companies Conducting a Business Combination that Results in a Change of Control with respect to the shares of Public Company Common Stock to be issued pursuant to this Agreement (the "NASDAQ Listing Application") and (v) such other consents, authorizations, orders, filings, approvals and registrations that, individually or in the aggregate, if not obtained or made, would not result in a loss of a material benefit to, or the creation of any material liability for, Public Company or Otic Pharma as a result of the Transaction.

(d) The affirmative vote in favor of the issuance of shares of Public Company Common Stock in the Transaction by the holders of a majority of the shares of Public Company Common Stock present or represented by proxy and voting at the Public Company Meeting is the only vote of the holders of any class or series of Public Company's capital stock or other securities of Public Company necessary to approve the Public Company Voting Proposal. There are no bonds, debentures, notes or other indebtedness of Public Company having the right to vote (or convertible into, or exchangeable for, securities having the right to vote) on any matters on which stockholders of Public Company may vote.

4.5 SEC Filings; Financial Statements; Information Provided.

(a) Public Company has filed all registration statements, forms, reports, certifications and other documents required to be filed by Public Company with the SEC since September 18, 2014. All such registration statements, forms, reports and other documents (including those that Public Company may file after the date hereof until the Closing) are referred to herein as the "Public Company SEC Reports." All of the Public Company SEC Reports (A) were or will be filed on a timely basis, (B) at the time filed, complied, or will comply when filed, as to form in all material respects with the requirements of the Securities Act and the Exchange Act applicable to such Public Company SEC Reports and (C) did not or will not at the time they were or are filed contain any untrue statement of a material fact or omit to state a material fact required to be stated in such Public Company SEC Reports or necessary in order to make the statements in such Public Company SEC Reports, in the light of the circumstances under which they were made, not misleading, in any material respect.

(b) Each of the consolidated financial statements (including, in each case, any related notes and schedules) contained or to be contained in the Public Company SEC Reports at the time filed (i) complied or will

Table of Contents

comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, (ii) were or will be prepared in accordance with GAAP applied on a consistent basis throughout the periods involved and at the dates involved (except as may be indicated in the notes to such financial statements or, in the case of unaudited interim financial statements, as permitted by the SEC on Form 10-Q under the Exchange Act) and (iii) fairly presented or will fairly present in all material respects the consolidated financial position of Public Company and its Subsidiaries as of the dates indicated and the consolidated results of its operations and cash flows for the periods indicated, except that the unaudited interim financial statements were or are subject to normal and recurring year-end adjustments. The consolidated balance sheet of Public Company as of September 30, 2016 is referred to herein as the “Public Company Balance Sheet.”

(c) PricewaterhouseCoopers LLP, Public Company’s current auditors, is and has been at all times since its engagement by Public Company (i) “independent” with respect to Public Company within the meaning of Regulation S-X and (ii) in compliance with subsections (g) through (l) of Section 10A of the Exchange Act (to the extent applicable) and the related rules of the SEC and the Public Company Accounting Oversight Board.

(d) The information to be supplied by or on behalf of Public Company for inclusion, or filed by the Public Company and incorporated by reference, in the Proxy Statement to be sent to the stockholders of Public Company in connection with the Public Company Meeting, which information shall be deemed to include all information about or relating to Public Company, the Public Company Voting Proposal or the Public Company Meeting, shall not, on the date the Proxy Statement is first mailed to stockholders of Public Company, or at the time of the Public Company Meeting, contain any statement that, at such time and in light of the circumstances under which it shall be made, is false or misleading with respect to any material fact, or omit to state any material fact necessary in order to make the statements made in the Proxy Statement not false or misleading; or omit to state any material fact necessary to correct any statement in any earlier communication with respect to the solicitation of proxies for the Public Company Meeting that has become false or misleading.

(e) Public Company does not have and never has had any sales in or revenues from the State of Israel.

4.6 No Undisclosed Liabilities. Public Company does not have any liability that is required to be set forth on a balance sheet of Public Company in accordance with GAAP, except for (a) liabilities shown on the Public Company Balance Sheet, (b) liabilities that have arisen since the date of the Public Company Balance Sheet in the Ordinary Course of Business, (c) liabilities for transaction expenses incurred in connection with the transactions contemplated by this Agreement and alternatives to such transactions, and (d) contractual and other liabilities incurred in the Ordinary Course of Business that are not required by GAAP to be reflected on a balance sheet.

4.7 Absence of Certain Changes or Events. During the period beginning on the date of the Public Company Balance Sheet and ending on the date hereof, Public Company and its Subsidiaries have conducted their respective businesses only in the Ordinary Course of Business and, since such date, there has not been (i) any change, event, circumstance, development or effect that, individually or in the aggregate, has had, or is reasonably likely to have, a Public Company Material Adverse Effect or (ii) any other action or event that would have required the consent of Otic Pharma pursuant to Section 5.2 (other than clause (A) of paragraph (j) or paragraphs (k) or (l) thereof) had such action or event occurred after the date of this Agreement.

4.8 Taxes.

(a) Each of Public Company and its Subsidiaries has properly filed on a timely basis all income and other material Tax Returns that it was required to file, and all such Tax Returns were true, correct and complete in all material respects. Each of Public Company and its Subsidiaries has paid on a timely basis all Taxes that were due and payable. The unpaid Taxes of Public Company and each of its Subsidiaries for Tax periods through

[Table of Contents](#)

the date of the Public Company Balance Sheet do not exceed the accruals and reserves for Taxes (excluding accruals and reserves for deferred Taxes established to reflect timing differences between book and Tax income) set forth on the Public Company Balance Sheet, and all unpaid Taxes of Public Company and each of its Subsidiaries for all Tax periods commencing after the date of the Public Company Balance Sheet arose in the Ordinary Course of Business. Neither Public Company nor any of its Subsidiaries is or has ever been a member of an affiliated group with which it has filed (or been required to file) consolidated, combined, unitary or similar Tax Returns, other than a group of which the common parent is Public Company. With the exception of customary commercial leases or contracts that are not primarily related to Taxes entered into in the Ordinary Course of Business and liabilities thereunder, neither Public Company nor any of its Subsidiaries (i) has any actual or potential liability under Treasury Regulations Section 1.1502-6 (or any comparable or similar provision of federal, state, local or foreign law), as a transferee or successor, pursuant to any contractual obligation, or otherwise for any Taxes of any person other than Public Company or any of its Subsidiaries, or (ii) is a party to or bound by any Tax indemnity, Tax sharing, Tax allocation or similar agreement. All material Taxes that Public Company or any of its Subsidiaries was required by law to withhold or collect have been duly withheld or collected and, to the extent required, have been properly paid to the appropriate Governmental Entity, and each of Public Company and its Subsidiaries has complied with all material information reporting and backup withholding requirements, including the maintenance of required records with respect thereto, in connection with amounts paid to any employee, independent contractor, creditor, or other third party.

(b) Public Company has delivered or made available to Otic Pharma (i) complete and correct copies of all Tax Returns of Public Company and any of its Subsidiaries relating to Taxes for all taxable periods for which the applicable statute of limitations has not yet expired, (ii) complete and correct copies of all private letter rulings, revenue agent reports, information document requests, notices of proposed deficiencies, deficiency notices, protests, petitions, closing agreements, settlement agreements, pending ruling requests and any similar documents submitted by, received by, or agreed to by or on behalf of Public Company or any of its Subsidiaries relating to Taxes for all taxable periods for which the statute of limitations has not yet expired, and (iii) complete and correct copies of all material agreements, rulings, settlements or other Tax documents with or from any Governmental Entity relating to Tax incentives of Otic Pharma or any of its Subsidiaries. No examination or audit of any Tax Return of Public Company or any of its Subsidiaries by any Governmental Entity is currently in progress or, to the knowledge of Public Company, threatened or contemplated. Neither Public Company nor any of its Subsidiaries has been informed in writing by any jurisdiction in which Public Company or any Subsidiary does not file a Tax Return that the jurisdiction believes that Public Company or any of its Subsidiaries was required to file any Tax Return that was not filed or is subject to Tax in such jurisdiction. Neither Public Company nor any of its Subsidiaries has (i) waived any statute of limitations with respect to Taxes or agreed to extend the period for assessment or collection of any Taxes, which waiver or extension is still in effect, (ii) requested any extension of time within which to file any Tax Return, other than routine extensions available as a matter of right which Tax Return has not yet been filed, or (iii) executed or filed any power of attorney with any taxing authority, which is still in effect.

(c) Neither Public Company nor any of its Subsidiaries has made any payment, is obligated to make any payment, or is a party to any agreement that could obligate it to make any payment that may be treated as an “excess parachute payment” under Section 280G of the Code (without regard to Sections 280G(b)(4) and 280G(b)(5) of the Code).

(d) Neither Public Company nor any of its Subsidiaries has been a United States real property holding corporation within the meaning of Section 897(c)(2) of the Code during the applicable period specified in Section 897(c)(1)(A)(i) of the Code.

(e) Neither Public Company nor any of its Subsidiaries has distributed to its stockholders or security holders stock or securities of a controlled corporation, nor has stock or securities of Public Company or any of its Subsidiaries been distributed, in a transaction to which Section 355 of the Code applies (i) in the two years prior to the date of this Agreement or (ii) in a distribution that could otherwise constitute part of a “plan” or “series of

[Table of Contents](#)

related transactions” (within the meaning of Section 355(e) of the Code) that includes the transactions contemplated by this Agreement.

(f) There are no Liens with respect to Taxes upon any of the assets or properties of Public Company or any of its Subsidiaries, other than with respect to Taxes not yet due and payable.

(g) Neither Public Company nor any of its Subsidiaries will be required to include any item of income in, or exclude any item of deduction from, taxable income for any period (or any portion thereof) ending after the Closing Date as a result of any (i) adjustments under Section 481 of the Code (or any similar adjustments under any provision of the Code or the corresponding foreign, state or local Tax laws), (ii) deferred intercompany gain or any excess loss account described in Treasury Regulations under Section 1502 of the Code (or any corresponding provision of state, local or foreign Tax law), (iii) closing agreement as described in Section 7121 of the Code (or any corresponding or similar provision of state, local or foreign Tax law) executed on or prior to the Closing Date, (iv) installment sale or other open transaction disposition made on or prior to the Closing Date, (v) prepaid amount received on or prior to the Closing Date, or (vi) any election made pursuant to Section 108(i) of the Code on or prior to the Closing Date.

(h) Neither Public Company nor any of its Subsidiaries has participated in any “reportable transaction” as defined in Section 1.6011-4(b) of the Treasury Regulations or any analogous provision of state or local law.

(i) Neither Public Company nor any Subsidiary (i) is a party to any joint venture, partnership, or other arrangement that is treated as a partnership for federal income Tax purposes, (ii) has made an entity classification (“check-the-box”) election under Section 7701 of the Code, (iii) is a stockholder of a “controlled foreign corporation” as defined in Section 957 of the Code (or any similar provision of state, local or foreign law), or (iv) is a stockholder in a “passive foreign investment company” within the meaning of Section 1297 of the Code.

(j) Neither Public Company nor any Subsidiary (A) has or has had a permanent establishment in any country (other than its country of incorporation) as defined in any applicable Tax treaty or convention between such country and Public Company or its Subsidiary’s country of incorporation or (B) has or has had operations constituting doing business for Tax purposes in any country (other than its country of incorporation).

(k) All related party transactions involving Public Company or any of its Subsidiaries have been conducted at arm’s length in compliance with Section 482 of the Code and the Treasury Regulations promulgated thereunder and any comparable provisions of any other Tax law. Each of Public Company and its Subsidiaries has maintained documentation (including any applicable transfer pricing studies) in connection with such related party transactions in accordance with Sections 482 and 6662 of the Code and the Treasury Regulations promulgated thereunder and any comparable provisions of any other Tax law.

4.9 Owned and Leased Real Properties.

(a) Neither Public Company nor any of its Subsidiaries owns or has ever owned any real property.

(b) Section 4.9(b) of the Public Company Disclosure Schedule sets forth a complete and accurate list of all real property leased, subleased or licensed by Public Company or any of its Subsidiaries as of the date of this Agreement (collectively, the “Public Company Leases”) and the location of the premises. Neither Public Company nor any of its Subsidiaries nor, to the knowledge of Public Company, any other party is in breach or default and no event has occurred, is pending or, to the knowledge of Public Company, is threatened, which, after the giving of notice, with lapse of time, or otherwise, would constitute any such breach or default under any of under any of the Public Company Leases, except where the existence of such defaults, individually or in the aggregate, has not had, and is not reasonably likely to result in, the loss of a material right or in a material

Table of Contents

liability of Public Company or any of its Subsidiaries. Neither Public Company nor any of its Subsidiaries leases, subleases or licenses any real property to any person other than Public Company and its Subsidiaries. Public Company has made available to Otic Pharma complete and accurate copies of all Public Company Leases.

4.10 Intellectual Property.

(a) To the knowledge of Public Company, Public Company and its Subsidiaries own, license or otherwise possess legally enforceable rights, free and clear of any Liens, to use all material Intellectual Property used or necessary to conduct the business of Public Company and its Subsidiaries as currently conducted, or that would be used or necessary as such business is currently proposed to be conducted (excluding generally commercially available software programs).

(b) The execution and delivery of this Agreement and consummation of the Transaction will not result in the breach of, or create on behalf of any third party the right to terminate or modify, (i) any license, sublicense or other agreement relating to any Intellectual Property owned by Public Company or any of its Subsidiaries that is material to the business of Public Company and its Subsidiaries, taken as a whole, including software that is used in the development or manufacture of or forms a part of any product or service sold by or expected to be sold by Public Company or any of its Subsidiaries, but excluding generally commercially available software programs (such Intellectual Property, the "Public Company Intellectual Property") or (ii) any license, sublicense and other agreement as to which Public Company or any of its Subsidiaries is a party and pursuant to which Public Company or any of its Subsidiaries is authorized to use any third party Intellectual Property that is material to the business of Public Company and its Subsidiaries, taken as a whole, including software that is used in the development or manufacture of or forms a part of any product or service sold by or expected to be sold by Public Company or any of its Subsidiaries, but excluding generally commercially available software programs (such Intellectual Property, the "Public Company Third Party Intellectual Property"). Section 4.10(b)(i) of the Public Company Disclosure Schedule sets forth a complete and accurate list of all Patent Rights and registrations and applications for Trademarks and copyrights included in the Public Company Intellectual Property and Section 4.10(b)(ii) sets forth a complete and accurate list of all agreements under which the Public Company or any of its Subsidiaries have in-licensed any Public Company Third Party Intellectual Property.

(c) To the knowledge of Public Company, all issued patents and registrations for Trademarks, service marks and copyrights which are owned by or licensed to Public Company or any of its Subsidiaries and that are material to the business of Public Company and its Subsidiaries, taken as a whole, are valid and subsisting and all payments due and all registration and renewal formalities relating to the Public Company Intellectual Property are up to date, complete and correct. Public Company and its Subsidiaries have taken reasonable measures to protect the proprietary nature of the Public Company Intellectual Property. To the knowledge of Public Company, as of the date of this Agreement (i) no other person or entity is infringing, violating or misappropriating any of the Public Company Intellectual Property or Public Company Third Party Intellectual Property and (ii) no claim or demand has been made in writing and no proceeding has been filed or is threatened in writing asserting that such Intellectual Property is invalid or unenforceable.

(d) To the knowledge of Public Company, none of the (i) products previously or currently sold by Public Company or any of its Subsidiaries or (ii) business or activities previously or currently conducted by Public Company or any of its Subsidiaries infringes, violates or constitutes a misappropriation of, any Intellectual Property of any third party. As of the date of this Agreement, neither Public Company nor any of its Subsidiaries has received any written complaint, claim or notice alleging any such infringement, violation or misappropriation.

4.11 Contracts.

(a) As of the date of this Agreement, there are no Contracts that are material contracts (as defined in Item 601(b)(10) of Regulation S-K) with respect to Public Company, other than those Contracts identified or described in the Public Company SEC Reports filed prior to the date hereof.

[Table of Contents](#)

(b) Public Company has not entered into any transaction that would be subject to proxy statement disclosure pursuant to Item 404 of Regulation S-K other than as disclosed in an SEC Report filed prior to the date hereof.

(c) Neither Public Company nor any of its Subsidiaries is a party to any agreement under which a third party would be entitled to receive a license or any other right to Public Company Intellectual Property as a result of the transactions contemplated by this Agreement.

(d) Section 4.11(d) of the Public Company Disclosure Schedule lists the following Contracts of Public Company and its Subsidiaries in effect as of the date of this Agreement:

(i) any Contract (or group of related Contracts) for the purchase or sale of products or for the furnishing or receipt of services (A) which calls for performance over a period of more than 180 days from the date of this Agreement, (B) which involves an aggregate of more than \$150,000 or (C) in which Public Company or any of its Subsidiaries has granted manufacturing rights, “most favored nation” pricing provisions or marketing or distribution rights relating to any products or territory or has agreed to purchase a minimum quantity of goods or services or has agreed to purchase goods or services exclusively from a particular party;

(ii) any Contract under which the consequences of a default or termination would reasonably be likely to have a Public Company Material Adverse Effect;

(iii) any Contract that could reasonably be expected to have the effect of prohibiting or impairing the conduct of the business of Otic Pharma or any of its Subsidiaries or Public Company or any of its Subsidiaries as currently conducted and as currently proposed to be conducted;

(iv) any Contract under which Public Company or any of its Subsidiaries is restricted from selling, licensing or otherwise distributing any of its technology or products, or providing services to, customers or potential customers or any class of customers, in any geographic area, during any period of time or any segment of the market or line of business;

(v) any dealer, distribution, joint marketing, joint venture, joint development, partnership, strategic alliance, collaboration, development agreement or outsourcing arrangement;

(vi) any Contract for the conduct of research studies, pre-clinical or clinical studies, manufacturing, distribution, supply, marketing or co-promotion of any products in development by or which has been or which is being marketed, distributed, supported, sold or licensed out, in each case by or on behalf of Public Company or any of its Subsidiaries; and

(vii) any Contract that would entitle any third party to receive a license or any other right to intellectual property of Otic Pharma or any of Otic Pharma’s Affiliates following the Closing.

(e) Public Company has made available to Otic Pharma a complete and accurate copy of each Contract listed in Sections 4.10(b)(i), 4.10(b)(ii) and 4.11(d) of the Public Company Disclosure Schedule. With respect to each Contract so listed and those Contracts identified or described in the Public Company SEC Reports filed prior to the date hereof: (i) the Contract is legal, valid, binding and enforceable and in full force and effect against Public Company and/or its Subsidiaries, as applicable, and, to the knowledge of Public Company, against each other party thereto, as applicable, subject to the Bankruptcy and Equity Exception; (ii) the Contract will continue to be legal, valid, binding and enforceable and in full force and effect against Public Company and/or its Subsidiaries, as applicable, and, to the knowledge of Public Company, against each other party thereto, immediately following the Closing in accordance with the terms thereof as in effect immediately prior to the Closing (other than any such Contracts that expire or terminate before such time in accordance with their terms and not as a result of a breach or default by Public Company or any of its Subsidiaries), in each case subject to

Table of Contents

the Bankruptcy and Equity Exception; and (iii) none of Public Company, its Subsidiaries nor, to the knowledge of Public Company, any other party, is in breach or violation of, or default under, any such Contract, and no event has occurred, is pending or, to the knowledge of Public Company, is threatened, which, with or without notice or lapse of time, or both, would constitute a breach or default by Public Company, its Subsidiaries or, to the knowledge of Public Company, any other party under such Contract, except for such breaches, violations or defaults that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect.

4.12 Litigation. There is no action, suit, proceeding, claim, arbitration or investigation before any Governmental Entity or before any arbitrator that is pending or has been threatened in writing against Public Company or any of its Subsidiaries that (a) seeks either damages in excess of \$100,000 or equitable relief or (b) in any manner seeks material injunctive or other non-monetary relief, including but not limited to a challenge or request to prevent, enjoin, alter or delay the transactions contemplated by this Agreement, except for such actions, suits, proceedings, claims, arbitrations or investigations first arising after the date of this Agreement that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect. There are no material judgments, orders or decrees outstanding against Public Company or any of its Subsidiaries.

4.13 Environmental Matters. Except for such matters that, individually or in the aggregate, have not had, and are not reasonably likely to have, a Public Company Material Adverse Effect:

(i) Public Company and its Subsidiaries have complied with all applicable Environmental Laws;

(ii) the properties currently owned, leased or operated by Public Company and its Subsidiaries (including soils, groundwater, surface water, buildings or other structures) are not contaminated with any Hazardous Substances;

(iii) the properties formerly owned, leased or operated by Public Company or any of its Subsidiaries were not contaminated with Hazardous Substances during the period of ownership, use or operation by Public Company or any of its Subsidiaries;

(iv) neither Public Company nor any of its Subsidiaries are subject to liability for any Hazardous Substance disposal or contamination on the property of any third party; and

(v) neither Public Company nor any of its Subsidiaries have released any Hazardous Substance into the environment.

(b) As of the date of this Agreement, neither Public Company nor any of its Subsidiaries has received any written notice, demand, letter, claim or request for information alleging that Public Company or any of its Subsidiaries may be in violation of, liable under or have obligations under, any Environmental Law.

(c) Neither Public Company nor any of its Subsidiaries is subject to any orders, decrees, injunctions or other arrangements with any Governmental Entity or is subject to any indemnity or other agreement with any third party relating to liability under any Environmental Law or relating to Hazardous Substances.

4.14 Employee Benefit Plans.

(a) Section 4.14(a) of the Public Company Disclosure Schedule sets forth a complete and accurate list of all Employee Benefit Plans maintained, or contributed to, by Public Company or any of its Subsidiaries or any of their respective ERISA Affiliates for the benefit of, or relating to, any current or former employee or other service provider of the Public Company or any of its Subsidiaries (together, the "Public Company Employee Plans").

[Table of Contents](#)

(b) With respect to each Public Company Employee Plan, Public Company has made available to Otic Pharma, a complete and accurate copy of (i) such plan (or a written summary of any unwritten plan), (ii) the three (3) most recent annual reports (Form 5500) filed with the IRS, (iii) each trust agreement, group annuity contract and summary plan description, if any, relating to such Public Company Employee Plan, (iv) the three (3) most recent financial statements for each Public Company Employee Plan that is funded, (v) all personnel, payroll and employment manuals and policies, (vi) all employee handbook, (vii) all reports regarding the satisfaction of the nondiscrimination requirements of Sections 410(b), 401(k) and 401(m) of the Code and (viii) any non-routine correspondence to or from the IRS, Department of Labor or other regulator concerning any Public Company Employee Plan, including any voluntary corrections submissions.

(c) Each Public Company Employee Plan has been administered in all material respects in accordance with ERISA, the Code and all other applicable laws and the regulations thereunder and in accordance with its terms and each of Public Company and its Subsidiaries and their respective ERISA Affiliates has in all material respects met its obligations with respect to such Public Company Employee Plan and has made all required contributions thereto (or reserved such contributions on the Public Company Balance Sheet). Public Company and its Subsidiaries and each of their respective ERISA Affiliates and each Public Company Employee Plan are in compliance in all material respects with the currently applicable provisions of ERISA and the Code and the regulations thereunder (including Section 4980B of the Code, Subtitle K, Chapter 100 of the Code and Sections 601 through 608 and Section 701 et seq. of ERISA). All filings and reports as to each Public Company Employee Plan required to have been submitted to the IRS or to the United States Department of Labor have been timely submitted. There is no audit, investigation or other proceeding (including any voluntary correction application) pending against or involving any Public Company Employee Plan. There have been no events with respect to any Public Company Employee Plan that could result in payment or assessment by or against Public Company or any of its Subsidiaries of any Taxes, including (but without limitation) any excise Taxes under Sections 4972, 4975, 4976, 4977, 4979, 4980B, 4980D, 4980E, 4980H or 5000 of the Code. With respect to the Public Company Employee Plans, no event has occurred, and to the knowledge of Public Company, there exists no condition or set of circumstances in connection with which Public Company or any of its Subsidiaries could be subject to any liability that is reasonably likely, individually or in the aggregate, to have a Public Company Material Adverse Effect under ERISA, the Code or any other applicable law.

(d) With respect to the Public Company Employee Plans, there are no benefit obligations for which contributions have not been made or properly accrued and there are no benefit obligations that have not been accounted for by reserves, or otherwise properly footnoted in accordance with GAAP, on the financial statements of Public Company, which obligations are reasonably likely, individually or in the aggregate, to have a Public Company Material Adverse Effect. The assets of each Public Company Employee Plan that is funded are reported at their fair market value on the books and records of such Public Company Employee Plan.

(e) All Public Company Employee Plans that are intended to be qualified under Section 401(a) of the Code have received determination letters from the IRS to the effect that such Public Company Employee Plans are qualified and the plans and trusts related thereto are exempt from federal income taxes under Sections 401(a) and 501(a) of the Code, respectively, of the Code, no such determination letter has been revoked and revocation has not been threatened, and no such Public Company Benefit Plan has been amended or operated since the date of its most recent determination letter or application therefor in any respect, and no act or omission has occurred, that would adversely affect its qualification or materially increase its cost. Each Public Company Employee Plan that is required to satisfy Section 401(k)(3) or Section 401(m)(2) of the Code had been tested for compliance with, and satisfies the requirements of, Section 401(k)(3) and Section 401(m)(2) of the Code, as the case may be, for each plan year ending prior to the Closing Date.

(f) Neither Public Company nor any of its Subsidiaries nor any of their respective ERISA Affiliates has (i) ever maintained a Public Company Employee Benefit Plan that was ever subject to Section 412 of the Code or Title IV of ERISA or (ii) ever been obligated to contribute to a “multiemployer plan” (as defined in Section 4001(a)(3) of ERISA). No Public Company Employee Plan is funded by, associated with or related to a

[Table of Contents](#)

“voluntary employees’ beneficiary association” within the meaning of Section 501(c)(9) of the Code. No Public Company Employee Plan holds securities issued by Public Company or any of its Subsidiaries or any of their respective ERISA Affiliates.

(g) Each Public Company Employee Plan is amendable and terminable unilaterally by Public Company and any of Public Company’s Subsidiaries and their respective ERISA Affiliates that are a party thereto or covered thereby at any time without liability to Public Company or any of its Subsidiaries or their respective ERISA Affiliates as a result thereof (other than for benefits accrued through the date of termination or amendment and reasonable administrative expenses related thereto), and no Public Company Employee Plan, plan documentation or agreement, summary plan description or other written communication distributed generally to employees by its terms prohibits Public Company or any of its Subsidiaries or their respective ERISA Affiliates from amending or terminating any such Public Company Employee Plan. The investment vehicles used to fund the Public Company Employee Plans may be changed at any time without incurring a material sales charge, surrender fee or other similar expense.

(h) Neither Public Company nor any of its Subsidiaries nor any of their respective ERISA Affiliates is a party to any oral or written (i) agreement with any stockholders, director, executive officer or other key employee of Public Company or any of its Subsidiaries (A) the benefits of which are contingent, or the terms of which are materially altered, upon the occurrence of a transaction involving Public Company or any of its Subsidiaries of the nature of any of the transactions contemplated by this Agreement, (B) providing any term of employment or compensation guarantee or (C) providing severance benefits or other benefits after the termination of employment of such director, executive officer or key employee; (ii) agreement, plan or arrangement under which any person may receive payments from Public Company or any of its Subsidiaries or their respective ERISA Affiliates that may be subject to the tax imposed by Section 4999 of the Code or included in the determination of such person’s “parachute payment” under Section 280G of the Code, without regard to Section 280G(b)(4); (iii) agreement providing any person providing for “tax gross up” or tax indemnifications related to Sections 280G or 409A of the Code or otherwise; or (iv) agreement or plan binding Public Company or any of its Subsidiaries or any of their respective ERISA Affiliates, including any stock option plan, stock appreciation right plan, restricted stock plan, stock purchase plan or severance benefit plan, any of the benefits of which shall be increased, or the vesting of the benefits of which shall be accelerated, by the occurrence of any of the transactions contemplated by this Agreement or the value of any of the benefits of which shall be calculated on the basis of any of the transactions contemplated by this Agreement. There are no loans or extensions of credit by Public Company, any of its Subsidiaries or any of their respective ERISA Affiliate to any employee or any other service provider to Public Company or any of its Subsidiaries.

(i) None of the Public Company Employee Plans promises or provides post-termination medical or other post-termination welfare benefits to any person, except as required by applicable law and at the sole expense of the participant.

(j) Public Company and its Subsidiaries are in material compliance with all applicable provisions of the Affordable Care Act, including reporting requirements, and there has been no change in health plan terms or coverage that would reasonably be expected to attract an excise tax under Section 4980H of the Code for the current year.

(k) Each Public Company Employee Plan that is a “nonqualified deferred compensation plan” (as defined in Section 409A(d)(1) of the Code) materially complies in form and operation with Section 409A of the Code and all IRS regulations and other guidance thereunder. No event has occurred that would be treated by Section 409A(b) of the Code as a transfer of property for purposes of Section 83 of the Code. Since January 1, 2005, no stock option or equity unit option granted under any Public Company Employee Plan has an exercise price that has been or may be less than the fair market value of the underlying stock or equity units (as the case may be) as of the date such option was granted or has any feature for the deferral of compensation other than the deferral of recognition of income until the later of exercise or disposition of such option. No nonqualified

[Table of Contents](#)

deferred compensation plan has been administered in a manner that would cause an excise tax to apply to payments to plan participants.

4.15 Compliance With Laws. Public Company and each of its Subsidiaries has complied in all material respects with, is not in material violation of, and, as of the date of this Agreement, has not received any notice alleging any material violation with respect to, any applicable provisions of any statute, law or regulation with respect to the conduct of its business, or the ownership or operation of its properties or assets.

4.16 Permits and Regulatory Matters.

(a) Public Company and each of its Subsidiaries have all material Permits required to conduct their businesses as currently conducted, including all such Permits required by the FDA or any other Governmental Entity exercising comparable authority (the "Public Company Authorizations").

(b) Public Company and its Subsidiaries are in compliance in all material respects with the terms of the Public Company Authorizations. No Public Company Authorization shall cease to be effective as a result of the consummation of the transactions contemplated by this Agreement.

(c) All manufacturing, processing, distribution, labeling, storage, testing, specifications, sampling, sale or marketing of products performed by or on behalf of Public Company or any of its Subsidiaries are in compliance in all material respects with all applicable laws, rules, regulations or orders administered or issued by the FDA or any other Governmental Entity exercising comparable authority. As of the date of this Agreement, neither Public Company nor any of its Subsidiaries has received any written notices or correspondence from the FDA or any other Governmental Entity exercising comparable authority, and to the knowledge of Public Company there is no action or proceeding pending or threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case alleging that Public Company or any of its Subsidiaries is not currently in compliance with any and all applicable laws, regulations or orders implemented by the FDA or any other Governmental Entity exercising comparable authority.

(d) There are no seizures, recalls, market withdrawals, field notifications or corrective actions, notifications of misbranding or adulteration, destruction orders, safety alerts or similar actions relating to the safety or efficacy of any products marketed or sold by Public Company or any of its Subsidiaries being conducted, requested in writing or, to the knowledge of Public Company, threatened by the FDA or any other Governmental Entity exercising comparable authority. Public Company has not, either voluntarily or involuntarily, initiated, conducted or issued or caused to be initiated, conducted or issued any recall, market withdrawal, safety alert or other similar notice or action relating to the alleged lack of safety or efficacy of any products marketed or sold by Public Company or any of its Subsidiaries.

(e) The studies, tests and preclinical and clinical trials conducted by or on behalf of Public Company or any of its Subsidiaries were and, if still pending, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards; and, as of the date of this Agreement, neither Public Company nor any of its Subsidiaries has received any written notices or correspondence from the FDA or any other Governmental Entity exercising comparable authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of Public Company or any of its Subsidiaries.

4.17 Employees.

(a) All current and past key employees of Public Company or any of its Subsidiaries have entered into confidentiality and assignment of inventions agreements with Public Company, a copy or form of which has previously been made available to Otic Pharma. To the knowledge of Public Company, as of the date of this Agreement, no employee of Public Company or any Subsidiary of Public Company is in violation of any term of

Table of Contents

any patent disclosure agreement, non-competition agreement, or any restrictive covenant to a former employer relating to the right of any such employee to be employed by Public Company or any of its Subsidiaries because of the nature of the business currently conducted by Public Company or any of its Subsidiaries or to the use of trade secrets or proprietary information of others. To the knowledge of Public Company, as of the date of this Agreement, no key employee or group of employees has any plans to terminate employment with Public Company or its Subsidiaries.

(b) Neither Public Company nor any of its Subsidiaries is a party to or otherwise bound by any collective bargaining agreement, contract or other agreement or understanding with a labor union or labor organization. Neither Public Company nor any of its Subsidiaries is the subject of any proceeding asserting that Public Company or any of its Subsidiaries has committed an unfair labor practice or is seeking to compel it to bargain with any labor union or labor organization, nor is there pending or, to the knowledge of Public Company, threatened, any labor strike, dispute, walkout, work stoppage, slow-down or lockout involving Public Company or any of its Subsidiaries.

4.18 Insurance. Public Company and its Subsidiaries maintain those insurance policies listed on Section 4.18 of the Public Company Disclosure Schedule, setting forth the type of policy, the effective date, the expiration date, the policy limits and deductible or retention amounts for each such policy (the “Public Company Insurance Policies”). Each Public Company Insurance Policy is in full force and effect. None of the Public Company Insurance Policies shall terminate or lapse (or be affected in any other adverse manner) by reason of any of the transactions contemplated by this Agreement. Public Company and each of its Subsidiaries have complied in all material respects with the provisions of each Public Company Insurance Policy under which it is the insured party. No insurer under any Public Company Insurance Policy has cancelled or generally disclaimed liability under any such policy or indicated any intent to do so or not to renew any such policy. All claims under the Public Company Insurance Policies have been filed in a timely fashion. All material claims pending under the Public Company Insurance Policies as of the date of this Agreement are listed on Section 4.18 of the Public Company Disclosure Schedule (the “Pending Claims”), setting forth the general nature of such claims (including claimant(s) and damages sought), the date on which the claim(s) arose and the expenses incurred to date under the retention or deductible.

4.19 Opinion of Financial Advisor. The financial advisor of Public Company, Wedbush PacGrow (the “Public Company Financial Advisor”), has delivered to Public Company an opinion dated the date of this Agreement to the effect, as of such date, that the consideration to be paid by Public Company in connection with the Transaction is fair, from a financial point of view, to Public Company, a signed copy of which opinion will be delivered to Otic Pharma within one Business Day following the date of this Agreement.

4.20 Section 203 of the DGCL. Assuming the accuracy of the representations and warranties of Otic Pharma in Section 3.24, Public Company Board has taken all actions so that the restrictions contained in Section 203 of the DGCL applicable to a “business combination” (as defined in Section 203) shall not apply to the execution, delivery or performance of this Agreement, the Public Company Support Agreement or the consummation of the Transaction or the other transactions contemplated by this Agreement or the Public Company Support Agreement.

4.21 Brokers: Fees and Expenses. No agent, broker, investment banker, financial advisor or other firm or person is or shall be entitled, as a result of any action, agreement or commitment of Public Company or any of its Subsidiaries, to any broker’s, finder’s, financial advisor’s or other similar fee or commission in connection with any of the transactions contemplated by this Agreement, except the Public Company Financial Advisor. Public Company has made available to Otic Pharma a complete and accurate copy of all agreements pursuant to which the Public Company Financial Advisor is entitled to any fees and expenses in connection with any of the transactions contemplated by this Agreement. Public Company is not a party to any agreements with the Public Company Financial Advisor providing the Public Company Financial Advisor with any rights after the Closing that have not been made available to Otic Pharma.

[Table of Contents](#)

4.22 Controls and Procedures, Certifications and Other Matters.

(a) Public Company and each of its Subsidiaries maintains accurate books and records reflecting its assets and liabilities and maintains proper and adequate internal control over financial reporting designed to provide assurance that (i) transactions are executed with management's authorization, (ii) transactions are recorded as necessary to permit preparation of the consolidated financial statements of Public Company and to maintain accountability for Public Company's consolidated assets, (iii) access to assets of Public Company and its Subsidiaries is permitted only in accordance with management's authorization, (iv) the reporting of assets of Public Company and its Subsidiaries is compared with existing assets at regular intervals and (v) accounts, notes and other receivables and inventory were recorded accurately, and proper and adequate procedures are implemented to effect the collection thereof on a current and timely basis.

(b) Public Company maintains disclosure controls and procedures required by Rules 13a-15 or 15d-15 under the Exchange Act, and such controls and procedures are effective to ensure that all material information concerning Public Company and its Subsidiaries is made known on a timely basis to the individuals responsible for the preparation of Public Company's filings with the SEC and other public disclosure documents.

(c) Neither Public Company nor any of its Subsidiaries has, since Public Company became subject to the reporting requirements of Section 13 or Section 15(d) of the Exchange Act, extended or maintained credit, arranged for the extension of credit, modified or renewed an extension of credit, in the form of a personal loan or otherwise, to or for any director or executive officer of Public Company. Section 4.22(c) of the Public Company Disclosure Schedule identifies any loan or extension of credit maintained by Public Company to which the second sentence of Section 13(k)(1) of the Exchange Act applies.

4.23 Books and Records. The minute books and other similar records of Public Company contain complete and accurate records of all material actions taken at any meetings of Public Company's stockholders, Board of Directors or any committee thereof and of all written consents executed in lieu of the holding of any such meeting. The books and records of Public Company accurately reflect in all material respects the assets, liabilities, business, financial condition and results of operations of Public Company and have been maintained in accordance with good business and bookkeeping practices.

4.24 No Other Representations or Warranties. Public Company hereby acknowledges and agrees that, except for the representations and warranties contained in this Agreement, none of Otic Pharma nor any other person on behalf of Otic Pharma makes any express or implied representation or warranty with respect to Otic Pharma or with respect to any other information provided to Public Company or any of its Affiliates in connection with the transactions contemplated hereby, and (subject to the express representations and warranties of Otic Pharma set forth in Article III (in each case as qualified and limited by the Otic Pharma Disclosure Schedule)) none of Public Company or any of its Affiliates, stockholders, directors, officers, employees, agents, representatives or advisors, or any other person, has relied on any such information (including the accuracy or completeness thereof).

ARTICLE V

CONDUCT OF BUSINESS

5.1 Covenants of Otic Pharma. Except as set forth in Section 5.1 of the Otic Pharma Disclosure Schedule or as expressly provided herein or as consented to in writing by Public Company (which consent shall not be unreasonably withheld, conditioned or delayed), from and after the date of this Agreement until the earlier of the termination of this Agreement in accordance with its terms and the Closing, Otic Pharma shall, and shall cause each of its Subsidiaries to, act and carry on its business in the Ordinary Course of Business, pay its debts and Taxes and perform its other obligations when due (subject to good faith disputes over such debts, Taxes or obligations), comply with applicable laws, rules and regulations, and use commercially reasonable efforts,

[Table of Contents](#)

consistent in all material respects with past practices, to maintain and preserve its and each of its Subsidiaries' business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others having business dealings with it. Without limiting the generality of the foregoing, except as set forth in Section 5.1 of the Otic Pharma Disclosure Schedule, from and after the date of this Agreement until the earlier of the termination of this Agreement in accordance with its terms and the Closing, Otic Pharma shall not, and shall not permit any of its Subsidiaries to, directly or indirectly, do any of the following without the prior written consent of Public Company (which consent shall not, in the case of the actions set forth in clauses (k) and (l) of this Section 5.1, be unreasonably withheld, conditioned or delayed):

(a) (i) declare, set aside or pay any dividends on, or make any other distributions (whether in cash, securities or other property) in respect of, any of its capital stock (other than dividends and distributions by a direct or indirect wholly owned Subsidiary of Otic Pharma to its parent); (ii) split, combine or reclassify any of its capital stock or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock or any of its other securities; or (iii) purchase, redeem or otherwise acquire any shares of its capital stock or any other of its securities or any rights, warrants or options to acquire any such shares or other securities, other than, in the case of this clause (iii), from former employees, directors and consultants in accordance with agreements in effect on the date of this Agreement providing for the repurchase of shares at no or nominal consideration in connection with any termination of services to Otic Pharma or any of its Subsidiaries;

(b) except as permitted by Section 5.1(l), issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any shares of its capital stock, any other voting securities or any securities convertible into or exchangeable for, or any rights, warrants or options to acquire, any such shares, voting securities or convertible or exchangeable securities (other than the issuance of shares of Otic Pharma Ordinary Shares upon the exercise of Otic Pharma Share Options or Otic Pharma Warrants outstanding on the date of this Agreement in accordance with their present terms (including cashless exercises) or Otic Pharma Share Options granted as contemplated by Section 5.1(l));

(c) amend its certificate of incorporation, bylaws or other comparable charter or organizational documents;

(d) except for purchases of inventory, raw materials and, to the extent the cost thereof is not in excess of \$100,000 in the aggregate, equipment, in each case in the Ordinary Course of Business, acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or (ii) any assets that are material, in the aggregate, to Otic Pharma and its Subsidiaries, taken as a whole;

(e) except in the Ordinary Course of Business, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets of Otic Pharma or of any of its Subsidiaries;

(f) whether or not in the Ordinary Course of Business, sell, dispose of or otherwise transfer any assets material to Otic Pharma and its Subsidiaries, taken as a whole (including any accounts, leases, contracts or intellectual property or any assets or the stock of any of its Subsidiaries, but excluding the sale or license of products in the Ordinary Course of Business);

(g) (i) incur or suffer to exist any indebtedness for borrowed money other than such indebtedness that existed as of the date of the Otic Pharma Balance Sheet to the extent reflected on the Otic Pharma Balance Sheet or guarantee any such indebtedness of another person, provided, however, that if the Closing does not occur on or prior to March 1, 2017, Otic Pharma shall have the right, in its sole discretion, to incur up to an aggregate of \$3,000,000 of additional indebtedness from the Shareholders on the terms set forth in Section 5.1(g)

[Table of Contents](#)

of the Otic Pharma Disclosure Schedule, (ii) issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Otic Pharma or any of its Subsidiaries, guarantee any debt securities of another person, enter into any “keep well” or other agreement to maintain any financial statement condition of another person or enter into any arrangement having the economic effect of any of the foregoing, (iii) make any loans, advances (other than routine advances to employees of Otic Pharma in the Ordinary Course of Business) or capital contributions to, or investment in, any other person, other than Otic Pharma or any of its direct or indirect wholly owned Subsidiaries or (iv) enter into any hedging agreement or other financial agreement or arrangement designed to protect Otic Pharma or its Subsidiaries against fluctuations in commodities prices or exchange rates;

(h) make any capital expenditures or other expenditures with respect to property, plant or equipment, other than as set forth in Otic Pharma’s budget for capital expenditures previously made available to Public Company or the specific capital expenditures disclosed and set forth in Section 5.1(h) of the Otic Pharma Disclosure Schedule;

(i) make any changes in accounting methods, principles or practices, except insofar as may have been required by a change in GAAP or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;

(j) except (i) in the Ordinary Course of Business or (ii) for terminations as a result of the expiration of any contract that expires in accordance with terms, (A) modify or amend in any material respect, or terminate, any material contract or agreement to which Otic Pharma or any of its Subsidiaries is party, or (B) knowingly waive, release or assign any material rights or claims (including any write-off or other compromise of any accounts receivable of Otic Pharma or any of its Subsidiaries);

(k) except in the Ordinary Course of Business, (i) enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products, of, or products licensed by, Otic Pharma or any of its Subsidiaries or (ii) license any material intellectual property rights to or from any third party;

(l) except as required to comply with applicable law or agreements, plans or arrangements existing on the date hereof and either disclosed in the Otic Pharma Disclosure Schedules or not required by this Agreement to be so disclosed, (i) take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, (ii) increase in any material respect the compensation or fringe benefits of, or pay any material bonus to, any director, officer, employee or consultant (except for annual increases of the salaries of non-officer employees in the Ordinary Course of Business), (iii) amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding options or restricted stock awards, (iv) pay any material benefit not provided for as of the date of this Agreement under any benefit plan, (v) grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan (including the grant of stock options, stock appreciation rights, stock based or stock related awards, performance units or restricted stock, or the removal of existing restrictions in any benefit plans or agreements or awards made thereunder), or (vi) take any action other than in the Ordinary Course of Business to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

(m) make or change any material Tax election, change an annual accounting period, enter into any closing agreement, waive or extend any statute of limitations with respect to Taxes, settle or compromise any material Tax liability, claim or assessment, surrender any right to claim a refund of material Taxes, or amend any income or other material Tax return;

(n) commence any offering of shares of Otic Pharma Ordinary Shares pursuant to any Employee Stock Purchase Plan;

[Table of Contents](#)

- (o) initiate, compromise or settle any material litigation or arbitration proceeding;
- (p) open or close any facility or office;
- (q) fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of this Agreement;
- (r) fail to pay accounts payable and other obligations in the Ordinary Course of Business;
- (s) suspend any clinical trials sponsored by Otic Pharma or involving any products marketed or in development by Otic Pharma;
- (t) permit the exercise of any Otic Pharma Share Options or Otic Pharma Warrants by any Person who is not a signatory to this Agreement, unless such Person first executes a joinder agreement agreeing to be bound by the terms of this Agreement in form and substance reasonable acceptable to Public Company; or
- (u) authorize any of, or commit or agree, in writing or otherwise, to take any of, the foregoing actions or any action that would make any representation or warranty of Otic Pharma in this Agreement untrue or incorrect in any material respect, or would materially impair or prevent the satisfaction of any conditions in Article VII hereof.

5.2 Covenants of Public Company. Except as set forth in Section 5.2 of the Public Company Disclosure Schedule or as expressly provided herein or as consented to in writing by Otic Pharma (which consent shall not be unreasonably withheld, conditioned or delayed), from and after the date of this Agreement until the earlier of the termination of this Agreement in accordance with its terms and the Closing, Public Company shall, and shall cause each of its Subsidiaries to, act and carry on its business in the Ordinary Course of Business, pay its debts and Taxes and perform its other obligations when due (subject to good faith disputes over such debts, Taxes or obligations), comply with applicable laws, rules and regulations, and, use commercially reasonable efforts, consistent in all material respects with past practices, to maintain and preserve its and each of its Subsidiaries' business organization, assets and properties, keep available the services of its present officers and key employees and preserve its advantageous business relationships with customers, strategic partners, suppliers, distributors and others having business dealings with it. Without limiting the generality of the foregoing, except as set forth on Section 5.2 of the Public Company Disclosure Schedule from and after the date of this Agreement until the earlier of the termination of this Agreement in accordance with its terms and the Closing, Public Company shall not, and shall not permit any of its Subsidiaries to, directly or indirectly, do any of the following without the prior written consent of Otic Pharma (which consent shall not, in the case of the actions set forth in clauses (k) and (l) of this Section 5.2, be unreasonably withheld, conditioned or delayed):

(a) (i) split, combine or reclassify any of its capital stock or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for shares of its capital stock or any of its other securities; or (ii) purchase, redeem or otherwise acquire any shares of its capital stock or any other of its securities or any rights, warrants or options to acquire any such shares or other securities, other than, in the case of this clause (ii), from former employees, directors and consultants in accordance with agreements in effect on the date of this Agreement providing for the repurchase of shares at no or nominal consideration in connection with any termination of services to Public Company or any of its Subsidiaries;

(b) issue, deliver, sell, grant, pledge or otherwise dispose of or encumber any shares of its capital stock, any other voting securities or any securities convertible into or exchangeable for, or any rights, warrants or options to acquire, any such shares, voting securities or convertible or exchangeable securities (in each case other than the issuance of shares of Public Company Common Stock upon the exercise of Public Company Stock Options or Public Company Warrants outstanding on the date of this Agreement in accordance with their present terms (including cashless exercises));

[Table of Contents](#)

(c) amend its certificate of incorporation, bylaws or other comparable charter or organizational documents;

(d) except for purchases of inventory and raw materials in the Ordinary Course of Business, acquire (i) by merging or consolidating with, or by purchasing all or a substantial portion of the assets or any stock of, or by any other manner, any business or any corporation, partnership, joint venture, limited liability company, association or other business organization or division thereof or (ii) any assets that are material, in the aggregate, to Public Company and its Subsidiaries, taken as a whole;

(e) except in the Ordinary Course of Business, sell, lease, license, pledge, or otherwise dispose of or encumber any properties or assets of Public Company or of any of its Subsidiaries;

(f) whether or not in the Ordinary Course of Business, sell, dispose of or otherwise transfer any assets material to Public Company and its Subsidiaries, taken as a whole (including any accounts, leases, contracts or intellectual property or any assets or the stock of any of its Subsidiaries, but excluding the sale or license of products in the Ordinary Course of Business);

(g) (i) incur or suffer to exist any indebtedness for borrowed money or guarantee any such indebtedness of another person, (ii) issue, sell or amend any debt securities or warrants or other rights to acquire any debt securities of Public Company or any of its Subsidiaries, guarantee any debt securities of another person, enter into any “keep well” or other agreement to maintain any financial statement condition of another person or enter into any arrangement having the economic effect of any of the foregoing, (iii) make any loans, advances (other than routine advances to employees of Public Company in the Ordinary Course of Business) or capital contributions to, or investment in, any other person, other than Public Company or any of its direct or indirect wholly owned Subsidiaries or (iv) enter into any hedging agreement or other financial agreement or arrangement designed to protect Public Company or its Subsidiaries against fluctuations in commodities prices or exchange rates;

(h) make any capital expenditures or other expenditures, other than (i) those contemplated by the Public Company financial model provided to Otic Pharma on the date hereof; provided that variances in any line item in the financial model shall be permitted to the extent the aggregate expenditures do not exceed the amount shown in the model (except as provided in clauses (ii) and (iii)), (ii) additional expenditures not exceeding 10% of the amount of aggregate expenditures shown in the model and (iii) expenditures incurred by the Public Company as a result of events or circumstances involving the Public Company’s ongoing clinical trials that arise outside of the Public Company’s control;

(i) make any changes in accounting methods, principles or practices, except insofar as may have been required by the SEC or a change in GAAP or, except as so required, change any assumption underlying, or method of calculating, any bad debt, contingency or other reserve;

(j) except (i) in the Ordinary Course of Business or (ii) for terminations as a result of the expiration of any contract that expires in accordance with its terms, (A) modify or amend in any material respect, or terminate, any material contract or agreement to which Public Company or any of its Subsidiaries is party, or (B) knowingly waive, release or assign any material rights or claims (including any write-off or other compromise of any accounts receivable of Public Company or any of its Subsidiaries);

(k) except in the Ordinary Course of Business, (i) enter into any material contract or agreement relating to the rendering of services or the distribution, sale or marketing by third parties of the products, of, or products licensed by, Public Company or any of its Subsidiaries or (ii) license any material intellectual property rights to or from any third party;

(l) except as required to comply with applicable law or agreements, plans or arrangements existing on the date hereof and either disclosed in the Public Company Disclosure Schedules, not required by this

[Table of Contents](#)

Agreement to be so disclosed or disclosed in the Public Company SEC Reports filed or furnished prior to the date of this Agreement, (i) take any action with respect to, adopt, enter into, terminate or amend any employment, severance or similar agreement or benefit plan for the benefit or welfare of any current or former director, officer, employee or consultant or any collective bargaining agreement, (ii) increase in any material respect the compensation or fringe benefits of, or pay any material bonus to, any director, officer, employee or consultant (except for annual increases of the salaries of non-officer employees in the Ordinary Course of Business), (iii) amend or accelerate the payment, right to payment or vesting of any compensation or benefits, including any outstanding options or restricted stock awards, (iv) pay any material benefit not provided for as of the date of this Agreement under any benefit plan, (v) grant any awards under any bonus, incentive, performance or other compensation plan or arrangement or benefit plan (including the grant of stock options, stock appreciation rights, stock based or stock related awards, performance units or restricted stock, or the removal of existing restrictions in any benefit plans or agreements or awards made thereunder), (vi) hire any additional officers or other employees, or any consultants or independent contractors, in each case, other than as set forth on Section 5.2(l) of the Public Company Disclosure Schedules and employees, consultants or independent contractors hired to fill open position created as a result of the separation of service of an officer, employee, consultant or independent contractor, as applicable, after the date of this Agreement, or (vii) take any action other than in the Ordinary Course of Business to fund or in any other way secure the payment of compensation or benefits under any employee plan, agreement, contract or arrangement or benefit plan;

(m) make or change any material Tax election, change an annual accounting period, enter into any closing agreement, waive or extend any statute of limitations with respect to Taxes, settle or compromise any material Tax liability, claim or assessment, surrender any right to claim a refund of material Taxes, or amend any income or other material Tax return;

(n) commence any offering of shares of Public Company Common Stock pursuant to any Employee Stock Purchase Plan;

(o) initiate, compromise or settle any material litigation or arbitration proceeding;

(p) open or close any facility or office;

(q) fail to use commercially reasonable efforts to maintain insurance at levels substantially comparable to levels existing as of the date of this Agreement;

(r) fail to pay accounts payable and other obligations in the Ordinary Course of Business; or

(s) authorize any of, or commit or agree, in writing or otherwise, to take any of, the foregoing actions or any action that would make any representation or warranty of Public Company in this Agreement untrue or incorrect in any material respect, or would materially impair or prevent the satisfaction of any conditions in Article VII hereof.

5.3 Confidentiality. The parties acknowledge that Public Company and Otic Pharma have previously executed a mutual non-disclosure agreement, dated as of September 6, 2016 (the "Confidentiality Agreement"), which Confidentiality Agreement shall continue in full force and effect in accordance with its terms, except as expressly modified by this Agreement.

ARTICLE VI

ADDITIONAL AGREEMENTS

6.1 No Solicitation

(a) No Solicitation or Negotiation. Except as set forth in this Section 6.1, until the Specified Time, each of Otic Pharma, Public Company and their respective Subsidiaries shall not, and each of Otic Pharma and

[Table of Contents](#)

Public Company shall use commercially reasonable efforts to cause their respective Representatives not to, directly or indirectly:

(i) solicit, seek or initiate or knowingly take any action to facilitate or encourage any offers, inquiries or the making of any proposal or offer that constitutes, or could reasonably be expected to lead to, any Acquisition Proposal;

(ii) enter into, continue or otherwise participate or engage in any discussions or negotiations regarding any Acquisition Proposal, or furnish to any person any non-public information or afford any person other than Public Company or Otic Pharma, as applicable, access to such party's property, books or records (except pursuant to a request by a Governmental Entity) in connection with any Acquisition Proposal; provided, however, that nothing in this Section 6.1 shall prevent a party or its Representatives from referring a person to this Section 6.1;

(iii) take any action to make the provisions of any takeover statute inapplicable to any transactions contemplated by an Acquisition Proposal; or

(iv) publicly propose to do any of the foregoing described in clauses (i) through (iii).

Notwithstanding the foregoing or anything to the contrary set forth in this Agreement, subject to compliance with Section 6.1(c), Public Company may (A) furnish non-public information with respect to Public Company and its Subsidiaries to any Qualified Person (and the Representatives of such Qualified Person), pursuant to a confidentiality agreement not materially less restrictive with respect to the confidentiality obligations of the Qualified Person than the Confidentiality Agreement, (B) engage in discussions or negotiations (including solicitation of revised Acquisition Proposals) with any Qualified Person (and the Representatives of such Qualified Person) regarding any such Acquisition Proposal or (C) amend, or grant a waiver or release under, any standstill or similar agreement with respect to any capital stock of such party with any Qualified Person. It is understood and agreed that any violation of the restrictions in this Section 6.1 (or action that, if taken by Public Company would constitute such a violation) by any Representatives of Public Company shall be deemed to be a breach of this Section 6.1 by Public Company.

(b) No Change in Recommendation or Alternative Acquisition Agreement.

Prior to the Specified Time:

(i) Public Company Board shall not, except as set forth in this Section 6.1, withhold, withdraw or modify, or publicly propose to withdraw or modify, its approval or recommendation with respect to the Public Company Voting Proposal (a "Public Company Board Recommendation Change");

(ii) each of Public Company and Otic Pharma shall not enter into any letter of intent, memorandum of understanding, agreement in principle, acquisition agreement, merger agreement or similar agreement (an "Alternative Acquisition Agreement") providing for the consummation of a transaction contemplated by any Acquisition Proposal (other than a confidentiality agreement referred to in Section 6.1(a) entered into in the circumstances referred to in Section 6.1(a)); and

(iii) each of the Public Company Board and the Otic Pharma Board, and each committee thereof, shall not, except as set forth in this Section 6.1, adopt, approve or recommend, or publicly propose to adopt, approve or recommend, any Acquisition Proposal.

Notwithstanding the foregoing or anything to the contrary set forth in this Agreement (including the provisions of this Section 6.1), at any time prior to the approval of the Public Company Voting Proposal, the Public Company Board may effect a Public Company Board Recommendation Change if: (i) the Public Company Board shall have determined in good faith (after consultation with outside legal counsel) that the failure to effect a Public Company Board Recommendation Change could reasonably be expected to be inconsistent with its fiduciary obligations under applicable law; (ii) Public Company has provided at least four

Table of Contents

Business Days prior written notice to Otic Pharma that it intends to effect a Public Company Board Recommendation Change, including a description in reasonable detail of the reasons for such recommendation change, and written copies of any relevant proposed transactions agreements with any party making a potential Superior Proposal (a “Recommendation Change Notice”) (it being understood that the Recommendation Change Notice shall not constitute a Public Company Board Recommendation Change for purposes of this Agreement); (iii) such party has complied in all material respects with the requirements of this Section 6.1 in connection with any potential Superior Proposal; and (iv) if the other party shall have delivered to such party a written, binding and irrevocable offer to alter the terms or conditions of this Agreement during the four Business Day period referred to in clause (ii) above, the Public Company Board of directors shall have determined in good faith (after consultation with outside legal counsel), after considering the terms of such offer by the other party, that the failure to effect a Public Company Board Recommendation Change could still reasonably be expected to be inconsistent with its fiduciary obligations under applicable law. In the event of any material amendment to any Superior Proposal (including any revision in the amount, form or mix of consideration Public Company’s stockholders would receive as a result of such potential Superior Proposal), Public Company shall be required to provide the other party with notice of such material amendment and there shall be a new two Business Day period following such notification during which the parties shall comply again with the requirements of this Section 6.1(b) and the Public Company Board shall not make a Public Company Board Recommendation Change prior to the end of any such period as so extended.

(c) Notices of Proposals. Each party will as promptly as reasonably practicable (and in any event within twenty-four (24) hours after receipt) (i) notify the other party of its receipt of any Acquisition Proposal and (ii) provide to the other party a copy of such Acquisition Proposal (if written), or a summary of the material terms and conditions of such Acquisition Proposal (if oral), including the identity of the Person making such Acquisition Proposal, and copies of all written communications with such Person with respect to such actual or potential Acquisition Proposal. Such party in receipt of an Acquisition Proposal shall notify the other party, in writing, of any decision of its board of directors as to whether to consider any Acquisition Proposal or to enter into discussions or negotiations concerning any Acquisition Proposal or to provide non-public information with respect to such to any person, which notice shall be given as promptly as practicable after such determination was reached (and in any event no later than one Business Day after such determination was reached). Such party in receipt of an Acquisition Proposal will (A) provide the other party with written notice setting forth such information as is reasonably necessary to keep the other party informed in all material respects of the status and material terms of any such Acquisition Proposal and of any material amendments or modifications thereto, (B) keep such other party informed as promptly as practicable with respect to any changes to the material terms of an Acquisition Proposal submitted to such party (and in any event within twenty-four (24) hours following any such changes), including by providing a copy of all written proposals and a summary of all oral proposals or material oral modifications to an earlier written proposal, in each case relating to any Acquisition Proposal, (C) prior to, or substantially concurrently with, the provision of any non-public information of such party to any such person, provide such information to the other party (including by posting such information to an electronic data room), to the extent such information has not previously been made available to the other party, and (D) promptly (and in any event within twenty-four (24) hours of such determination) notify the other party of any determination by such party’s board of directors that such Acquisition Proposal constitutes a Superior Proposal.

(d) Certain Permitted Disclosure. Notwithstanding anything to the contrary in this Agreement, nothing contained in this Agreement shall prohibit the Public Company Board from (i) taking and disclosing to its stockholders a position with respect to a tender offer contemplated by Rule 14d-9 or Rule 14e-2 promulgated under the Exchange Act, or from issuing a “stop, look and listen” statement pending disclosure of its position thereunder (none of which, in and of itself, shall be deemed to constitute a Public Company Board Recommendation Change), or (ii) making any disclosure to its stockholders if, in the good faith judgment of its board of directors, after consultation with outside counsel, failure to so disclose could be inconsistent with its obligations under applicable law; provided, however, that notwithstanding clauses (i) and (ii) of this Section 6.1(d), in no event shall Public Company, the Public Company Board, or any committee of the Public Company Board, take, or agree or resolve to take, any action prohibited by Section 6.1(b), except as expressly permitted by Section 6.1(b).

Table of Contents

(e) Cessation of Ongoing Discussions. Each of Public Company and Otic Pharma shall, and shall direct its Representatives to, cease immediately all discussions and negotiations that commenced prior to the date of this Agreement regarding any proposal that constitutes, or could reasonably be expected to lead to, an Acquisition Proposal; provided, however, that the foregoing shall not in any way limit or modify the rights of any party hereto under the other provisions of this Section 6.1. Public Company and Otic Pharma will immediately revoke or withdraw access of any person (other than the Public Company, Otic Pharma and their respective Representatives) to any data room (virtual or actual) containing any non-public information with respect to Public Company and request from each third party (other than the Public Company, Otic Pharma and their Representatives) the prompt return or destruction of all non-public information with respect to Public Company or Otic Pharma, as applicable, previously provided to such person.

(f) Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

“Acquisition Proposal” means, with respect to Public Company or Otic Pharma, (a) any inquiry, proposal or offer for a merger, consolidation, dissolution, sale of substantial assets, recapitalization, share exchange, tender offer or other business combination involving such party and its Subsidiaries (other than mergers, consolidations, recapitalizations, share exchanges or other business combinations involving solely such party and/or one or more Subsidiaries of such party), (b) any proposal for the issuance by such party of 15% or more of its equity securities or (c) any proposal or offer to acquire in any manner, directly or indirectly, 15% or more of the equity securities or consolidated total assets of such party and its Subsidiaries, in each case other than the transactions contemplated by this Agreement.

“Qualified Person” means any person making an unsolicited Acquisition Proposal that the Public Company Board determines in good faith (after consultation with outside counsel and its financial advisors) is, or could reasonably be expected to lead to, a Superior Proposal, and such Acquisition Proposal has not resulted from a material breach by Public Company of its obligations under Section 6.1(a).

“Superior Proposal” means, with respect to Public Company, any *bona fide*, unsolicited written proposal made by a third party to acquire 50% or more of the equity securities or consolidated total assets of such party and its Subsidiaries, pursuant to a tender or exchange offer, a merger, a consolidation, business combination or recapitalization or a sale or exclusive license of its assets, (a) on terms which the board of directors of such party determines in its good faith judgment to be more favorable to the holders of such party’s capital stock than the transactions contemplated by this Agreement (after consultation with its financial and legal advisors), taking into account all the terms and conditions of such proposal and this Agreement (including any termination or break-up fees and conditions to consummation, as well as any written, binding offer by the other party hereto to amend the terms of this Agreement, which offer is not revocable for at least three Business Days) that the board of directors of such party determines to be relevant and (b) which board of directors of such party has determined to be reasonably capable of being completed on the terms proposed, taking into account all financial, regulatory, legal and other aspects of such proposal that board of directors of such party determines to be relevant (including the likelihood and timing of consummation (as compared to the transactions contemplated hereby).

“Specified Time” means the earlier to occur of (a) the Closing, and (b) the time at which this Agreement is terminated in accordance with the terms hereof.

6.2 Proxy Statement.

(a) As promptly as practical after the execution of this Agreement, Public Company, with the cooperation of Otic Pharma, shall prepare and file with the SEC the Proxy Statement. Otic Pharma shall provide to Public Company as promptly as reasonably practical all information regarding Otic Pharma required to be included in the Proxy Statement. Public Company shall respond to any comments of the SEC on the preliminary

Table of Contents

filing(s) of the Proxy Statement and shall use commercially reasonable efforts to file the definitive version of the Proxy Statement as promptly as practicable, and Public Company shall cause the Proxy Statement to be mailed to its stockholders at the earliest practicable time after the SEC has completed its review of the preliminary filing of the Proxy Statement (or once 10 days after the initial filing of the preliminary Proxy Statement, if the SEC will not review the Proxy Statement). Public Company shall notify Otic Pharma promptly upon the receipt of any comments from the SEC or its staff and of any request by the SEC or its staff for amendments to the Proxy Statement or any filing pursuant to Section 6.2(b) or for additional information and shall supply Otic Pharma with copies of all correspondence between Public Company or any of its representatives, on the one hand, and the SEC, or its staff, on the other hand, with respect to the Proxy Statement or any filing pursuant to Section 6.2(b). Public Company shall use commercially reasonable efforts to cause all documents that it is responsible for filing with the SEC under this Section 6.2 to comply in all material respects with all applicable requirements of law and the rules and regulations promulgated thereunder. Whenever either Public Company or Otic Pharma shall become aware of the occurrence of any event which is required to be set forth in an amendment or supplement to the Proxy Statement or any filing pursuant to Section 6.2(b), Public Company or Otic Pharma, as the case may be, shall promptly inform the other of such occurrence and cooperate in filing with the SEC or its staff, and/or mailing to stockholders of Public Company and Otic Pharma, such amendment or supplement.

(b) Public Company shall promptly make all necessary filings required of Public Company with respect to the Transaction under the Securities Act, the Exchange Act, applicable state blue sky laws and the rules and regulations thereunder.

6.3 NASDAQ Listing. Public Company agrees to use its commercially reasonable efforts to continue the listing of Public Company Common Stock on NASDAQ during the term of this Agreement and to cause the shares of Public Company Common Stock being issued in connection with the Transaction to be approved for listing (subject to notice of issuance) on NASDAQ at or prior to the Closing, including by filing the NASDAQ Listing Application. Otic Pharma will cooperate with Public Company to cause the NASDAQ Listing Application to be approved and shall promptly furnish to Public Company all information concerning Otic Pharma and its equity holders that may be required or reasonably requested in connection with any action contemplated by this Section 6.3. To the extent necessary in order to maintain the listing of the Public Company Common Stock on NASDAQ (e.g., in order to meet the NASDAQ minimum bid price requirement), the Public Company shall seek stockholder approval for a reverse stock split as part of the Proxy Statement (the "NASDAQ Proposal"), with the specific terms for such split to be proposed by Public Company and approved by Otic Pharma (such approval not to be unreasonably withheld, conditioned or delayed).

6.4 Access to Information. Subject to compliance with applicable confidentiality obligations owed to third parties in effect as of the date of this Agreement, each of Public Company and Otic Pharma shall (and shall cause each of its Subsidiaries to) afford to the other party's officers, employees, accountants, counsel and other representatives, reasonable access, during normal business hours during the period prior to the Closing, to all its properties, books, contracts, commitments, personnel and records and, during such period, each of Public Company and Otic Pharma shall (and shall cause each of its Subsidiaries to) furnish promptly to the other party all information concerning its business, properties, assets and personnel as the other party may reasonably request. Each of Public Company and Otic Pharma will hold any such information which is nonpublic in confidence in accordance with the Confidentiality Agreement. No information or knowledge obtained in any investigation pursuant to this Section 6.4 or otherwise shall affect or be deemed to modify any representation or warranty contained in this Agreement or the conditions to the obligations of the parties to consummate the Transaction. Without limiting the generality of the foregoing, from the date of this Agreement until the Closing, each of Public Company and Otic Pharma shall promptly provide the other party with copies of: (a) unaudited monthly financial statements or management accounts, when available; (b) any written materials or communications sent by or on behalf of such party to its stockholders; (c) any notice, report or other document filed with or sent to, or received from, any Governmental Entity in connection with the Transaction or any of the other transactions contemplated by this Agreement; and (d) any material notice, report or other document received from any Governmental Entity.

[Table of Contents](#)

6.5 Stockholder Approval.

(a) Public Company, acting through the Public Company Board, shall take all actions in accordance with applicable law, its certificate of incorporation and bylaws and NASDAQ rules to duly call, give notice of, convene and hold as promptly as practicable, after the declaration of effectiveness of the Registration Statement, the Public Company Stockholders Meeting for the purpose of considering and voting upon the Public Company Voting Proposal as well as the NASDAQ Proposal, if any. Subject to Section 6.1(b), the Public Company Board shall include in the Proxy Statement the recommendation of the Public Company Board in favor of approval of the Public Company Voting Proposal. Public Company shall take all action that is both reasonable and lawful to solicit from its stockholders proxies in favor of the Public Company Voting Proposal. Notwithstanding anything to the contrary contained in this Agreement, Public Company, after consultation with Otic Pharma, may adjourn or postpone Public Company Stockholders Meeting to the extent necessary to ensure that any required supplement or amendment to the Proxy Statement is provided to Public Company's stockholders or, if as of the time for which the Public Company Stockholders Meeting is originally scheduled (as set forth in the Proxy Statement), there are insufficient shares of Public Company Common Stock represented (either in person or by proxy) to constitute a quorum necessary to conduct the business of the Public Company Stockholders Meeting.

(b) Notwithstanding the foregoing, nothing herein shall limit a party's right to terminate this Agreement pursuant to Section 8.1.

6.6 Legal Conditions to Transaction.

(a) Subject to the terms hereof, including Section 6.6(b), Otic Pharma and Public Company shall each use commercially reasonable efforts to (i) take, or cause to be taken, all actions, and do, or cause to be done, and to assist and cooperate with the other parties in doing, all things necessary, proper or advisable to consummate and make effective the transactions contemplated hereby as promptly as practicable, (ii) as promptly as practicable, obtain from any Governmental Entity or any other third party any consents, licenses, permits, waivers, approvals, authorizations, or orders required to be obtained or made by Otic Pharma or Public Company or any of their Subsidiaries in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated hereby, (iii) as promptly as practicable, make all necessary filings, and thereafter make any other required submissions, with respect to this Agreement and the Transaction required under (A) the Securities Act and the Exchange Act, and any other applicable securities laws, and (B) any other applicable law and (iv) execute or deliver any additional instruments necessary to consummate the transactions contemplated by, and to fully carry out the purposes of, this Agreement. Otic Pharma and Public Company shall reasonably cooperate with each other in connection with the making of all such filings. Otic Pharma and Public Company shall use their respective commercially reasonable efforts to furnish to each other all information required for any application or other filing to be made pursuant to the rules and regulations of any applicable law (including all information required to be included in the Proxy Statement and the Registration Statement) in connection with the transactions contemplated by this Agreement.

(b) Each of Otic Pharma and Public Company shall give (or shall cause their respective Subsidiaries to give) any notices to third parties, and use, and cause their respective Subsidiaries to use, their commercially reasonable efforts to obtain any third party consents related to or required in connection with the Transaction that are (i) necessary to consummate the transactions contemplated hereby, (ii) disclosed or required to be disclosed in the Otic Pharma Disclosure Schedule or the Public Company Disclosure Schedule, as the case may be, or (iii) required to prevent the occurrence of an event that may have a Otic Pharma Material Adverse Effect or a Public Company Material Adverse Effect from occurring prior to or after the Closing.

6.7 Public Disclosure. Except as may be required by applicable law or stock market regulations, (i) the press release announcing the execution of this Agreement shall be issued only in such form as shall be mutually agreed upon by Public Company and Otic Pharma, (ii) Public Company shall use commercially reasonable efforts to consult with Otic Pharma before issuing any press release or otherwise making any public statement

Table of Contents

with respect to the Transaction or this Agreement and shall not issue any such press release or make any such public statement prior to using such efforts (provided, however, that these restrictions shall not apply to any communications by Public Company with respect to any Acquisition Proposal, Superior Proposal, Recommendation Change Notice or Public Company Board Recommendation Change) and (iii) Otic Pharma shall not issue any press release or otherwise make any public statement with respect to the Transaction or this Agreement without the prior written consent of Public Company.

6.8 Affiliate Legends. Section 6.8 of the Otic Pharma Disclosure Schedule sets forth a list of those persons who are, in Otic Pharma's reasonable judgment, "affiliates" of Otic Pharma within the meaning of Rule 145 promulgated under the Securities Act ("Rule 145 Affiliates"). Otic Pharma shall notify Public Company in writing regarding any change in the identity of its Rule 145 Affiliates prior to the Closing Date. Public Company shall be entitled to place appropriate legends on the certificates evidencing any shares of Public Company Common Stock to be received by Rule 145 Affiliates of Otic Pharma in the Transaction reflecting the restrictions set forth in Rule 145 promulgated under the Securities Act and to issue appropriate stop transfer instructions to the transfer agent for Public Company Common Stock.

6.9 Indemnification.

(a) From the Closing through the sixth anniversary of the Closing Date, Public Company shall indemnify and hold harmless each person who is now, or has been at any time prior to the date hereof, or who becomes prior to the Closing, a director or officer of Otic Pharma, Public Company or any of their respective Subsidiaries (the "Indemnified Persons"), against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, incurred in connection with any claim, action, suit, proceeding or investigation, whether civil, criminal, administrative or investigative, arising out of or pertaining to the fact that the Indemnified Person is or was an officer, director, employee or agent of Otic Pharma, Public Company or any of their respective Subsidiaries, or, while a director or officer of Otic Pharma, Public Company or any of their respective Subsidiaries, is or was serving at the request of Otic Pharma, Public Company or any of their respective Subsidiaries as a director, officer, employee or agent of another person, whether asserted or claimed prior to, at or after the Closing, to the fullest extent permitted by applicable law. Each Indemnified Person will be entitled to advancement of expenses (including attorneys' fees) incurred in the defense of any such claim, action, suit, proceeding or investigation from Public Company following receipt by Public Company from the Indemnified Person of a request therefor; provided that any person to whom expenses are advanced provides an undertaking, to the extent then required by the DGCL, to repay such advances if it is ultimately determined that such person is not entitled to indemnification. The certificate of incorporation and bylaws of the Public Company will contain provisions at least as favorable as the provisions relating to the indemnification, advance of expenses and elimination of liability for monetary damages set forth in the certificate of incorporation and bylaws of the Public Company on the date hereof.

(b) Public Company shall either (A) maintain in effect for six years after the Closing Date the Public Company's existing directors' and officers' insurance policies in place as of the date hereof, or (B) prior to the Closing, purchase a six-year "tail" policy under its own existing directors' and officers' liability insurance policy, with an effective date as of the Closing (provided that Public Company may substitute therefor a policy of at least the same coverage containing terms and conditions that are not less favorable in any material respect); provided, however, that in no event shall Public Company be required to expend pursuant to this Section 6.9(b) more than an amount equal to 200% of the current annual premiums paid by Public Company for such insurance; provided, further, that during the term of the "tail" policy, Public Company shall not take any action following the Closing to cause such "tail" policy to be cancelled or any provision therein to be amended or waived in any manner that would adversely affect in any material respect the rights of their former and current officers and directors.

(c) Public Company shall pay all expenses, including reasonable attorneys' fees, that may be incurred by a person in successfully enforcing such person's rights provided in this Section 6.9.

[Table of Contents](#)

(d) Public Company and Otic Pharma agree that all rights to exculpation, indemnification and advancement of expenses for acts or omissions occurring at or prior to the Closing, whether asserted or claimed prior to, at or after the Closing, now existing in favor of the current or former directors, officers or employees, as the case may be, of Public Company, Otic Pharma or any of their respective Subsidiaries as provided in their respective certificates of incorporation or by-laws or other organization documents or in any agreement shall survive the Transaction and shall continue in full force and effect. The provisions of this Section 6.9 are intended to be in addition to the rights otherwise available to the current officers and directors of Public Company, Otic Pharma or any of their respective Subsidiaries by law, charter, statute, by-law or agreement, and shall operate for the benefit of, and shall be enforceable by, each of the Indemnified Persons, their heirs and their representatives. The obligations set forth in this Section 6.9 shall not be terminated, amended or otherwise modified in any manner that adversely affects any Indemnified Person, or any person who is a beneficiary under the policies referred to in this Section 6.9 and their heirs and representatives, without the prior written consent of such affected Indemnified person or other person.

(e) If Public Company, Otic Pharma or any of their respective successors or assigns shall (i) consolidate with or merge into any other person and shall not be the continuing or surviving corporation or entity of such consolidation or merger, or (ii) transfer all or substantially all of its properties and assets to any person, then, and in each such case, proper provisions shall be made so that the successors and assigns of such person shall assume all of the obligations of such person set forth in this Section 6.9.

(f) Nothing in this Agreement is intended to, shall be construed to or shall release, waive or impair any rights to directors' and officers' insurance claims under any policy that is or has been in existence with respect to Otic Pharma, Public Company or any of their respective Subsidiaries for any of their respective directors, officers or other employees, it being understood and agreed that the indemnification provided for in this Section 6.9 is not prior to or in substitution for any such claims under such policies.

6.10 Notification of Certain Matters. Public Company shall give prompt notice to Otic Pharma, and Otic Pharma shall give prompt notice to Public Company, upon becoming aware of the occurrence, or failure to occur, of any event, which occurrence or failure to occur would be reasonably likely to cause (a) (i) any representation or warranty of such party contained in this Agreement that is qualified as to materiality to be untrue or inaccurate in any respect or (ii) any other representation or warranty of such party contained in this Agreement to be untrue or inaccurate in any material respect, in each case, at any time from and after the date of this Agreement until the Closing, or (b) any material failure of Public Company or Otic Pharma, as the case may be, or of any officer, director, employee or agent thereof, to comply with or satisfy any covenant, condition or agreement to be complied with or satisfied by it under this Agreement.

6.11 Corporate Identity. Promptly after the Closing, Public Company shall take all action necessary to cause its certificate of incorporation to be amended to reflect a change in Public Company's name to OticPharma, Inc.

6.12 Succession. Promptly after the Closing, Public Company shall take all action necessary to cause the persons identified on Schedule 6.12 of the Public Company Disclosure Schedule to be appointed as executive officers of Public Company.

6.13 Board of Directors of Public Company. Promptly after the Closing, Public Company shall take all action necessary (a) to cause the number of members of Public Company Board to be fixed at seven, (b) to cause three persons identified in writing by Otic Pharma to the Public Company no later than 15 Business Days after the date of this Agreement and one person identified in writing by Otic Pharma promptly following the Closing, in each case under this clause (b) reasonably acceptable to the Public Company, to be appointed to Public Company Board, and (c) to cause, effective at the time of such appointment, either (i) the resignations of three members of the Public Company Board or (ii) the resignations of four members of the Public Company Board and the appointment to the Public Company Board of one person identified in writing by the Public Company to

[Table of Contents](#)

Otic Pharma no later than 15 Business Days after the date of this Agreement, in each case under this clause (c) reasonably acceptable to Otic Pharma.

6.14 Employee Communications. Public Company and Otic Pharma will use reasonable efforts to consult with each other, and will consider in good faith each other's advice, prior to sending any notices or other communication materials to its employees regarding this Agreement, the Transaction or the effects thereof on the employment, compensation or benefits of its employees.

6.15 State Takeover Laws. If any "fair price," "business combination" or "control share acquisition" statute or other similar statute or regulation is or may become applicable to any of the transactions contemplated by this Agreement, the parties hereto shall use their respective commercially reasonable efforts to (a) take such actions as are reasonably necessary so that the transactions contemplated hereunder may be consummated as promptly as practicable on the terms contemplated hereby and (b) otherwise take all such actions as are reasonably necessary to eliminate or minimize the effects of any such statute or regulation on such transactions.

6.16 Security Holder Litigation. Notwithstanding anything to the contrary herein, (a) Public Company shall have the right to control the defense and settlement of any litigation related to this Agreement, the Transaction or the other transactions contemplated by this Agreement brought by any stockholder or any holder of other securities of Public Company against Public Company and/or its directors or officers, provided that Public Company shall give Otic Pharma the opportunity to participate in the defense of any such litigation and shall not settle any such litigation (other than any settlement not requiring the payment of any amount to any third party in excess of the retentions or deductibles under any applicable insurance policies of Public Company) without the prior written consent of Otic Pharma (which consent shall not be unreasonably withheld, conditioned or delayed), and (b) Otic Pharma shall have the right to control the defense and settlement of any litigation related to this Agreement, the Transaction or the other transactions contemplated by this Agreement brought by any stockholder or any holder of other securities of Otic Pharma against Otic Pharma and/or its directors or officers, provided that Otic Pharma shall give Public Company the opportunity to participate in the defense of any such litigation and shall consider Public Company's advice with respect to such litigation.

6.17 Lock-Up: Regulation S.

(a) Until the date which is 180 days following the Closing Date, each Shareholder, the 104H Trustee or the 102 Trustee, as applicable, will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any securities of Public Company, including shares of Public Company Common Stock or securities convertible into or exchangeable or exercisable for any such securities, enter into a transaction which would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of such securities, whether any such aforementioned transaction is to be settled by delivery of such securities or such other securities, in cash or otherwise, or publicly disclose the intention to make any such offer, sale, pledge or disposition, or otherwise to enter into any such transaction, swap, hedge or other arrangement.

(b) Each Regulation S Shareholder agrees (i) not to, in connection with the transactions contemplated by this Agreement, engage in any "directed selling efforts" within the United States, as such term is defined in Regulation S under the Securities Act, (ii) not to resell any Public Company Common Stock received pursuant to this Agreement except in accordance with the provisions of Regulation S under the Securities Act, pursuant to an effective registration statement or pursuant to an available exemption from registration and agrees not to engage in hedging transactions with regard to such shares of Public Company Common Stock, (iii) that Public Company will not register any proposed transfer of any shares of Public Company Common Stock by such Shareholder to the extent such transfer is proposed to not be made in accordance with the provisions of Regulation S, pursuant to an effective registration statement or pursuant to an available exemption from registration and (iv) not to sell or offer to sell any shares of Public Company Common Stock to any "U.S. person" (as such term is defined in Regulation S under the Securities Act), or for the account

[Table of Contents](#)

or benefit of any “U.S. person” (as such term is defined in Regulation S under the Securities Act), in each case until the date that is six-months following the Closing Date.

ARTICLE VII

CONDITIONS TO TRANSACTION

7.1 Conditions to Each Party’s Obligation To Effect the Transaction. The respective obligations of each party to this Agreement to effect the Transaction shall be subject to the satisfaction prior to the Closing Date of the following conditions:

(a) Stockholder Approval. The Public Company Voting Proposal shall have been approved at the Public Company Meeting, at which a quorum is present, by the requisite vote of the stockholders of Public Company under applicable law and stock market regulation.

(b) Governmental Approvals. All authorizations, consents, including each of the Israeli Tax Rulings, orders or approvals of, or declarations or filings with, or expirations of waiting periods imposed by, any Governmental Entity in connection with the Transaction and the consummation of the other transactions contemplated by this Agreement, the failure of which to file, obtain or occur is reasonably likely to have a Public Company Material Adverse Effect or a Otic Pharma Material Adverse Effect, shall have been filed, been obtained or occurred on terms and conditions that would not reasonably be likely to have a Public Company Material Adverse Effect or a Otic Pharma Material Adverse Effect.

(c) No Injunctions. No Governmental Entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any order, executive order, stay, decree, judgment or injunction (preliminary or permanent) or statute, rule or regulation which is in effect and which has the effect of making the Transaction illegal or otherwise prohibiting consummation of the Transaction.

(d) NASDAQ Notification. The NASDAQ Listing Application shall have been approved.

7.2 Additional Conditions to the Obligations of Public Company. The obligations of Public Company to effect the Transaction shall be subject to the satisfaction on or prior to the Closing Date of each of the following additional conditions, any of which may be waived in writing exclusively by Public Company:

(a) Representations and Warranties. The representations and warranties of Otic Pharma set forth in this Agreement and in any certificate or other writing delivered by Otic Pharma pursuant hereto shall be true and correct (i) as of the date of this Agreement (except in the case of this clause (i), (A) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date and (B) where the failure to be true and correct (without regard to any materiality, Otic Pharma Material Adverse Effect or knowledge qualifications contained therein), individually or in the aggregate, has not had, and is not reasonably likely to have, a Otic Pharma Material Adverse Effect) and (ii) as of the Closing Date as though made on and as of the Closing Date (except in the case of this clause (ii), (A) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date, (B) for changes contemplated by this Agreement and (C) where the failure to be true and correct (without regard to any materiality, Otic Pharma Material Adverse Effect or knowledge qualifications contained therein), individually or in the aggregate, has not had, and is not reasonably likely to have, a Otic Pharma Material Adverse Effect); provided, however, that the representations and warranties made by Shareholders in Sections 2.1, 2.2(a) and 2.3 and the representations and warranties made by Otic Pharma in Sections 3.2, 3.4(a) and 3.7(i) shall not be subject to the qualification set forth in clause (C) above; provided, further, that the representations and warranties set forth in Section 3.2(a) shall be true and correct except for such inaccuracies as are in the aggregate de minimis.

[Table of Contents](#)

(b) Performance of Obligations of Shareholders and Otic Pharma. The Shareholders and Otic Pharma shall have performed in all material respects all obligations required to be performed by them under this Agreement on or prior to the Closing Date.

(c) No Otic Pharma Material Adverse Effect. No Otic Pharma Material Adverse Effect shall have occurred since the date of this Agreement and be continuing.

(d) Third Party Consents. Otic Pharma shall have obtained (i) all consents and approvals of third parties listed in Section 7.2(d)(i) of the Otic Pharma Disclosure Schedule and (ii) any other required consent or approval of any third party (other than a Governmental Entity) the failure of which to obtain, individually or in the aggregate, is reasonably likely to have a Otic Pharma Material Adverse Effect (it being understood and agreed that the failure to obtain or effect any or all of the consents and approvals listed in Section 7.2(d)(ii) of the Otic Pharma Disclosure Schedule will not be reasonably likely to have a Otic Pharma Material Adverse Effect).

(e) Resignations. Public Company shall have received copies of the resignations, effective as of the Closing, of each director of Otic Pharma and its Subsidiaries.

(f) Officers' Certificate. Public Company shall have received an officers' certificate duly executed by each of the Chief Executive Officer and Chief Financial Officer of Otic Pharma to the effect that the conditions of Sections 7.2(a), (b) and (c) have been satisfied.

7.3 Additional Conditions to the Obligations of Otic Pharma. The obligation of Otic Pharma to effect the Transaction shall be subject to the satisfaction on or prior to the Closing Date of each of the following additional conditions, any of which may be waived, in writing, exclusively by Otic Pharma:

(a) Representations and Warranties. The representations and warranties of Public Company set forth in this Agreement and in any certificate or other writing delivered by Public Company pursuant hereto shall be true and correct (i) as of the date of this Agreement (except in the case of this clause (i), (A) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date and (B) where the failure to be true and correct (without regard to any materiality, Public Company Material Adverse Effect or knowledge qualifications contained therein), individually or in the aggregate, has not had, and is not reasonably likely to have, a Public Company Material Adverse Effect) and (ii) as of the Closing Date as though made on and as of the Closing Date (except in the case of this clause (ii), (A) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date, (B) for changes contemplated by this Agreement and (C) where the failure to be true and correct (without regard to any materiality, Public Company Material Adverse Effect or knowledge qualifications contained therein), individually or in the aggregate, has not had, and is not reasonably likely to have, a Public Company Material Adverse Effect); provided, however, that the representations and warranties made by Public Company in Sections 4.2, 4.4(a), 4.4(d) and 4.7(i) shall not be subject to the qualification set forth in clause (C) above; provided, further, that the representations and warranties set forth in Section 4.2(a) shall be true and correct except for such inaccuracies as are in the aggregate de minimis.

(b) Performance of Obligations of Public Company. Public Company shall have performed in all material respects all obligations required to be performed by them under this Agreement on or prior to the Closing Date.

(c) No Public Company Material Adverse Effect. No Public Company Material Adverse Effect shall have occurred since the date of this Agreement and be continuing.

(d) Third Party Consents. Public Company shall have obtained (i) all consents and approvals of third parties listed in Section 7.3(d)(i) of the Public Company Disclosure Schedule and (ii) any other consent or

[Table of Contents](#)

approval of any third party (other than a Governmental Entity) the failure of which to obtain, individually or in the aggregate, is reasonably likely to have an Public Company Material Adverse Effect (it being understood and agreed that the failure to obtain or effect any or all of the consents and approvals listed in Section 7.3(d)(ii) of the Public Company Disclosure Schedule will not be reasonably likely to have a Public Company Material Adverse Effect).

(e) Resignations. Otic Pharma shall have received copies of the resignations, effective as of the Closing, of the directors of Public Company who will not continue to serve in such roles after the Closing.

(f) Israeli Tax Rulings. Otic Pharma shall have prepared, filed and received all Israeli Tax Rulings with respect to the transactions contemplated hereunder.

(g) Office of the Chief Scientist. The Public Company shall have delivered to Otic Pharma an executed copy of an undertaking in the standard form required by the OCS from non-Israeli residents investing in Israeli companies which have received support from the OCS, substantially in the form attached hereto as Exhibit C (the "OCS Undertaking").

(h) Officers' Certificate. Otic Pharma shall have received an officers' certificate duly executed by each of the Chief Executive Officer and Chief Financial Officer of Public Company to the effect that the conditions of Sections 7.3(a), (b), and (c) have been satisfied.

ARTICLE VIII

TERMINATION AND AMENDMENT

8.1 Termination. This Agreement may be terminated at any time prior to the Closing (with respect to Sections 8.1(b) through 8.1(k), by written notice by the terminating party to the other party), whether before or, subject to the terms hereof, after approval of the Transaction by the stockholders of Otic Pharma or Public Company:

(a) by mutual written consent of Public Company and Otic Pharma;

(b) by either Public Company or Otic Pharma if the Transaction shall not have been consummated by April 30, 2016 (the "Outside Date") (provided that the right to terminate this Agreement under this Section 8.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been a principal cause of or resulted in the failure of the Transaction to occur on or before the Outside Date);

(c) by either Public Company or Otic Pharma if a Governmental Entity of competent jurisdiction shall have issued a non-appealable final order, decree or ruling or taken any other non-appealable final action, in each case having the effect of permanently restraining, enjoining or otherwise prohibiting the Transaction; provided, however, that a party hereto shall not be permitted to terminate this Agreement pursuant to this Section 8.1(c) if the issuance of any such order, decree, ruling or other action is attributable to the failure of such party (or any Affiliate of such party) to perform in any material respect any covenant in this Agreement required to be performed by such party (or any Affiliate of such party) at or prior to the Closing;

(d) by either Public Company or Otic Pharma if at the Public Company Meeting (including any adjournment or postponement permitted by this Agreement), at which a vote on the Public Company Voting Proposal is taken, the requisite vote of the stockholders of Public Company in favor of Public Company Voting Proposal shall not have been obtained;

(e) by Public Company, if Otic Pharma shall have knowingly and materially breached its obligations under Section 6.1 of this Agreement;

[Table of Contents](#)

(f) by Otic Pharma, if at any time prior to the receipt of the Public Company Stockholder Approval: (i) Public Company Board shall have failed to give its recommendation to the approval of the Public Company Voting Proposal in the Proxy Statement or shall have withdrawn or modified its recommendation of the Public Company Voting Proposal; (ii) Public Company Board (or any committee thereof) shall have approved or recommended to the stockholders of Public Company an Acquisition Proposal; (iii) a tender offer or exchange offer for outstanding shares of Public Company Common Stock is commenced (other than by Otic Pharma or an Affiliate of Otic Pharma), and Public Company Board (or any committee thereof) recommends that the stockholders of Public Company tender their shares in such tender or exchange offer or, within ten Business Days after the commencement of such tender offer or exchange offer, Public Company Board fails to recommend against acceptance of such offer; or (iv) Public Company shall have knowingly and materially breached its obligations under Section 6.1 or Section 6.5(b) of this Agreement;

(g) by Public Company, if there has been a material breach of or failure to perform any representation, warranty, covenant or agreement set forth in this Agreement (other than those referred to elsewhere in this Section 8.1) on the part of Otic Pharma, which breach would cause the conditions set forth in Section 7.2(a) or (b) not to be satisfied; provided that Public Company is not then in material breach of any representation, warranty or covenant under this Agreement and provided, further, that if such breach or failure to perform is curable by Otic Pharma, as applicable, then this Agreement shall not terminate pursuant to this Section 8.1(g) as a result of such particular breach or failure until the earlier of the Outside Date or the expiration of a thirty (30) day period commencing upon delivery of written notice from Public Company to Otic Pharma of such breach or failure, and it being understood that this Agreement shall not terminate pursuant to this Section 8.1(g) as a result of such particular breach or violation if such breach or violation is cured prior to such termination becoming effective;

(h) by Otic Pharma, if there has been a material breach of or failure to perform any representation, warranty, covenant or agreement set forth in this Agreement (other than those referred to elsewhere in this Section 8.1) on the part of Public Company, which breach would cause the conditions set forth in Section 7.3(a) or (b) not to be satisfied; provided that Otic Pharma is not then in material breach of any representation, warranty or covenant under this Agreement and provided, further, that if such breach or failure to perform is curable by Public Company, then this Agreement shall not terminate pursuant to this Section 8.1(h) as a result of such particular breach or failure until the earlier of the Outside Date or the expiration of a thirty (30) day period commencing upon delivery of written notice from Otic Pharma to Public Company of such breach or failure, and it being understood that this Agreement shall not terminate pursuant to this Section 8.1(h) as a result of such particular breach or violation if such breach or violation is cured prior to such termination becoming effective;

(i) [Intentionally omitted]

(j) [Intentionally omitted]

(k) by Public Company if, at any time prior to the receipt of the Public Company Stockholder Approval, each of the following occur: (A) Public Company shall have received a Superior Proposal; (B) Public Company shall have complied in all material respects with its obligations under Section 6.1 in order to accept such Superior Proposal; (C) the Public Company Board approves, and Public Company concurrently with the termination of this Agreement enters into, a definitive agreement with respect to such Superior Proposal; and (D) prior to or concurrently with such termination, Public Company pays to Otic Pharma the amount contemplated by Section 8.3(c).

8.2 Effect of Termination. In the event of termination of this Agreement as provided in Section 8.1, this Agreement shall immediately become void and there shall be no liability or obligation on the part of Public Company, Otic Pharma, or their respective officers, directors, stockholders or Affiliates; provided that (a) any such termination shall not relieve any party from liability for any knowing and intentional breach of this Agreement and (b) the provisions of Sections 3.20 and 4.21 (Brokers; Fees and Expenses), Section 5.3

[Table of Contents](#)

(Confidentiality), this Section 8.2 (Effect of Termination), Section 8.3 (Fees and Expenses) and Article IX (Miscellaneous) of this Agreement and the Confidentiality Agreement shall remain in full force and effect and survive any termination of this Agreement.

8.3 Fees and Expenses.

(a) Except as set forth in this Section 8.3, all fees and expenses incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the party incurring such expenses, whether or not the Transaction is consummated.

(b) Otic Pharma shall pay Public Company a termination fee of \$1,500,000 (the "Otic Pharma Termination Fee") in the event of the termination of this Agreement:

(i) by Public Company pursuant to Sections 8.1(e); or

(ii) by Public Company pursuant to Section 8.1(g).

(c) Public Company shall pay Otic Pharma a termination fee of \$1,000,000 (the "Public Company Termination Fee") in the event of the termination of this Agreement:

(i) by Otic Pharma pursuant to Section 8.1(f);

(ii) by Public Company pursuant to Section 8.1(k); or

(iii) by Public Company or Otic Pharma, as applicable, pursuant to Sections 8.1(b) or 8.1(h), so long as (A) prior to the termination of this Agreement, any person makes an Acquisition Proposal or amends an Acquisition Proposal made prior to the date of this Agreement with respect to Public Company; and (B) within 12 months after such termination Public Company enters into a definitive agreement to consummate, or consummates, any Acquisition Proposal (regardless of whether made before or after the termination of this Agreement); provided that for purposes of this Section 8.3(c)(iii), the references to 15% in the definition of Acquisition Proposal shall be deemed to be 50%.

(d) Any fee due under Section 8.3(b)(i) or 8.3(c)(i) shall be paid by wire transfer of same day funds within one Business Day of the date of termination of this Agreement. Any fee due under Section 8.3(b)(ii) or 8.3(c)(ii) shall be paid by wire transfer of same day funds on the date of termination of this Agreement (and shall be a condition to the effectiveness of such termination). Any fee due under Section 8.3(c)(iii) shall be paid by wire transfer of same-day funds within two Business Days after the date on which the transaction referenced in Section 8.3(c)(iii)(B) is consummated. If one party fails to promptly pay to the other any expense reimbursement or fee due hereunder, the defaulting party shall pay the costs and expenses (including legal fees and expenses) in connection with any action, including the filing of any lawsuit or other legal action, taken to collect payment, together with interest on the amount of any unpaid fee at the publicly announced prime rate of Bank of America, N.A. plus five percent per annum, compounded quarterly, from the date such expense reimbursement or fee was required to be paid.

(e) The parties hereto acknowledge that the agreements contained in this Section 8.3 are an integral part of the transactions contemplated by this Agreement, and that, without these agreements, the parties hereto would not enter into this Agreement. Notwithstanding Section 8.2 or any other provision of this Agreement, payment of the termination fees described in this Section 8.3 shall constitute the sole and exclusive remedy of Public Company or Otic Pharma, as applicable in connection with any termination of this Agreement in the circumstances in which such fees became payable. In the event that Public Company or Otic Pharma shall receive the payment of a termination fee, the receipt of such fee shall be deemed to be liquidated damages for any and all losses or damages suffered or incurred by Public Company and any of its Affiliates or Otic Pharma and any of its Affiliates, as applicable, or any other person in connection with this Agreement (and the

[Table of Contents](#)

termination hereof), the transactions contemplated hereby (and the abandonment thereof) or any matter forming the basis for such termination, and none of the Public Company, any of its Affiliates or Otic Pharma or any of its Affiliates, as applicable, or any other person, shall be entitled to bring or maintain any other claim, action or proceeding against Public Company or Otic Pharma, as applicable, or any of their respective Affiliates arising out of this Agreement, any of the transactions contemplated hereby or any matters forming the basis for such termination.

(f) The parties hereto acknowledge and agree that (i) in no event shall Otic Pharma be required to pay Otic Pharma Termination Fee on more than one occasion, nor shall Public Company be required to pay Public Company Termination Fee on more than one occasion and (ii) in each case whether or not such fee may be payable under more than one provision of this Agreement at the same or at different times and the occurrence of different events.

8.4 Amendment. This Agreement may be amended by the parties hereto, with respect to Public Company and Otic Pharma, by action taken or authorized by their respective Boards of Directors, and, with respect to the Shareholders, by action taken by the Shareholders holding a majority of the issued and outstanding Otic Pharma Share Capital, at any time before or after approval of the matters presented in connection with the Transaction by the stockholders of any of the parties, but, after any such approval, no amendment shall be made which by law requires further approval by such stockholders without such further approval. This Agreement may not be amended except by an instrument in writing signed on behalf of each of Public Company, Otic Pharma and the Shareholders holding a majority of the issued and outstanding Otic Pharma Share Capital.

8.5 Extension; Waiver. At any time prior to the Closing, Public Company or Otic Pharma, by action taken or authorized by their respective Boards of Directors, or the Shareholders holding a majority of the issued and outstanding Otic Pharma Share Capital, may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other parties hereto, (b) waive any inaccuracies in the representations and warranties contained herein or in any document delivered pursuant hereto and (c) waive compliance with any of the agreements or conditions contained herein. Any agreement on the part of a party hereto to any such extension or waiver shall be valid only if set forth in a written instrument signed on behalf of such party. Such extension or waiver shall not be deemed to apply to any time for performance, inaccuracy in any representation or warranty, or noncompliance with any agreement or condition, as the case may be, other than that which is specified in the extension or waiver. The failure of any party to this Agreement to assert any of its rights under this Agreement or otherwise shall not constitute a waiver of such rights.

8.6 Procedure for Termination, Amendment, Extension or Waiver. A termination of this Agreement pursuant to Section 8.1, an amendment, modification or supplement of this Agreement pursuant to Section 8.4 or an extension or waiver of this Agreement pursuant to Section 8.5 shall, in order to be effective, require action by the respective boards of directors of the applicable parties.

ARTICLE IX

MISCELLANEOUS

9.1 Non-survival of Representations, Warranties and Agreements. None of the representations, warranties, covenants and agreements in this Agreement shall survive the Closing, except for the agreements contained in Article I, Article II, Section 6.9, 6.12 and 6.13 and this Article IX. This Section 9.1 shall have no effect upon any other obligations of the parties hereto, whether to be performed before or after the consummation of the Transaction.

9.2 Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly delivered (i) three Business Days after being sent by registered or certified mail, return receipt requested,

[Table of Contents](#)

postage prepaid, or (ii) one Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable overnight courier service, in each case to the intended recipient as set forth below:

- (a) if to Public Company, to
- Tokai Pharmaceuticals, Inc.
Jodie P. Morrison
President and Chief Executive Officer
255 State Street, 6th Floor
Boston, MA 02109
- with a copy (which shall not constitute notice) to:
- Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attn: Stuart M. Falber, Esq.
Hal J. Leibowitz, Esq.
Telecopy: (617) 526-5000

- (b) if to Otic Pharma, to
- Otic Pharma, Ltd.
Gregory J. Flesher
Chief Executive Officer
19900 MacArthur Blvd., Suite 550
Irvine, California 92612
- with copies (which shall not constitute notice) to:
- Gibson, Dunn & Crutcher, LLP
555 Mission Street, Suite 3000
San Francisco, California 94105
Attn: Ryan A. Murr
- and
- Yigal Amon & Co.
22 Rivlin Street
Jerusalem 9424018, Israel
Attn: Barry Levenfeld

Any party to this Agreement may give any notice or other communication hereunder using any other means (including personal delivery, messenger service, telecopy, ordinary mail or electronic mail), but no such notice or other communication shall be deemed to have been duly given unless and until it actually is received by the party for whom it is intended. Any party to this Agreement may change the address to which notices and other communications hereunder are to be delivered by giving the other parties to this Agreement notice in the manner herein set forth.

9.3 Entire Agreement. This Agreement (including the Schedules and Exhibits hereto and the documents and instruments referred to herein that are to be delivered at the Closing) constitutes the entire agreement among the parties to this Agreement and supersedes any prior understandings, agreements or representations by or among the parties hereto, or any of them, written or oral, with respect to the subject matter hereof and the parties hereto expressly disclaim reliance on any such prior understandings, agreements or representations to the extent not embodied in this Agreement. Notwithstanding the foregoing, the Confidentiality Agreement shall remain in effect in accordance with its terms.

[Table of Contents](#)

9.4 No Third Party Beneficiaries. This Agreement is not intended to, and shall not, confer upon any other person any rights or remedies hereunder, except as set forth in or contemplated by the terms and provisions of Section 6.9.

9.5 Assignment. No party may assign any of its rights or delegate any of its performance obligations under this Agreement, in whole or in part, by operation of law or otherwise without the prior written consent of the other parties, and any such assignment without such prior written consent shall be null and void. Subject to the preceding sentence, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the parties hereto and their respective successors and permitted assigns. Any purported assignment of rights or delegation of performance obligations in violation of this Section 9.5 is void.

9.6 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the parties hereto agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties hereto agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term.

9.7 Counterparts and Signature. This Agreement may be executed in two or more counterparts (including by facsimile or by an electronic scan delivered by electronic mail), each of which shall be deemed an original but all of which together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each of the parties hereto and delivered to the other parties, it being understood that all parties need not sign the same counterpart. This Agreement may be executed and delivered by facsimile or by an electronic scan delivered by electronic mail.

9.8 Interpretation. When reference is made in this Agreement to an Article or a Section, such reference shall be to an Article or Section of this Agreement, unless otherwise indicated. The table of contents, table of defined terms and headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement. The language used in this Agreement shall be deemed to be the language chosen by the parties hereto to express their mutual intent, and no rule of strict construction shall be applied against any party. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns and pronouns shall include the plural, and vice versa. Any reference to any federal, state, local or foreign statute or law shall be deemed also to refer to all rules and regulations promulgated thereunder, unless the context requires otherwise. Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation." Where this Agreement refers to information that was "made available", that means that such information was either (i) provided directly to the Public Company or Otic Pharma, as applicable, by the other party, (ii) included in the virtual data rooms established by Public Company and Otic Pharma created for the purposes of providing information to the other party in connection with this Agreement at least three Business Days prior to the execution and delivery of this Agreement or (iii) solely with respect to information made available by Public Company, filed with and publicly available on the SEC's EDGAR system prior to the date of this Agreement. No summary of this Agreement prepared by any party shall affect the meaning or interpretation of this Agreement.

9.9 Governing Law. All matters arising out of or relating to this Agreement and the transactions contemplated hereby (including its interpretation, construction, performance and enforcement) shall be governed

[Table of Contents](#)

by and construed in accordance with the internal laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of laws of any jurisdictions other than those of the State of Delaware; provided, that this Agreement will be governed by and construed in accordance with the laws of the State of Israel solely to the extent necessary to effect the purchase by the Public Company and the sale by the Shareholders of the shares of Otic Pharma Share Capital and the transactions related thereto.

9.10 Remedies. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such party, and the exercise by a party of any one remedy will not preclude the exercise of any other remedy. The parties hereto agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, this being in addition to any other remedy to which they are entitled at law or in equity.

9.11 Submission to Jurisdiction. Each of the parties to this Agreement (a) consents to submit itself to the exclusive personal jurisdiction of the Court of Chancery of the State of Delaware, New Castle County, or, if that court does not have jurisdiction, a federal court sitting in Wilmington, Delaware in any action or proceeding arising out of or relating to this Agreement or any of the transactions contemplated by this Agreement, (b) agrees that all claims in respect of such action or proceeding shall be heard and determined in any such court, (c) agrees that it shall not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any such court and (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement or any of the transaction contemplated by this Agreement in any other court. Each of the parties hereto waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of any other party with respect thereto. Any party may make service on another party by sending or delivering a copy of the process to the party to be served at the address and in the manner provided for the giving of notices in Section 9.2. Nothing in this Section 9.11, however, shall affect the right of any party to serve legal process in any other manner permitted by law.

9.12 WAIVER OF JURY TRIAL. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE ACTIONS OF ANY PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT OF THIS AGREEMENT.

9.13 Disclosure Schedule. Each of the Otic Pharma Disclosure Schedule and the Public Company Disclosure Schedule shall be arranged in sections corresponding to the numbered sections contained in this Agreement, and the disclosure in any section shall qualify only (a) the corresponding section of this Agreement and (b) the other sections of this Agreement, to the extent that it is reasonably apparent from a reading of such disclosure that it also qualifies or applies to such other sections. The inclusion of any information in the Otic Pharma Disclosure Schedule or the Public Company Disclosure Schedule, as applicable, shall not be deemed to be an admission or acknowledgment, in and of itself, that such information is required by the terms hereof to be disclosed, is material, has resulted in or would result in a Otic Pharma Material Adverse Effect or a Public Company Material Adverse Effect, as applicable, or is outside the Ordinary Course of Business.

[Remainder of Page Intentionally Left Blank]

[Table of Contents](#)

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

TOKAI PHARMACEUTICALS, INC.

By: /s/ Jodie P. Morrison

Name: Jodie Morrison

Title: Chief Executive Officer

OTIC PHARMA, LTD.

By: /s/ Gregory Flesher

Name: Gregory Flesher

Title: Chief Executive Officer

[Table of Contents](#)

SHAREHOLDER

INCENTIVE II MANAGEMENT LTD.

By: /s/ Eyal Lifschitz, Boris Lifschitz

Name: Eyal Lifschitz, Boris Lifschitz

Title:

[Signature Page to Share Purchase Agreement]

[Table of Contents](#)

SHAREHOLDER

PURE ACOUSTICS INC.

By: /s/ Rami Ezratty

Name: Rami Ezratty

Title: President

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PEREGRINE VC INVESTMENTS II (ISRAEL), L.P.

By: /s/ Eyal Lifschitz, Boris Lifschitz

Name: Eyal Lifschitz, Boris Lifschitz

Peregrine Ventures

Management Ltd.

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PEREGRINE VC INVESTMENTS II (US INVESTORS), L.P.

By: /s/ Eyal Lifschitz, Boris Lifschitz

Name: Eyal Lifschitz, Boris Lifschitz

Peregrine Ventures

Management Ltd.

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PEREGRINE VC INVESTMENTS II (OTHER INVESTORS),
L.P.

By: /s/ Eyal Lifschitz, Boris Lifschitz

Name: Eyal Lifschitz, Boris Lifschitz
Peregrine Ventures
Management Ltd.

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PEREGRINE II MANAGEMENT LTD.

By: /s/ Eyal Lifschitz, Boris Lifschitz

Name: Eyal Lifschitz, Boris Lifschitz

Peregrine Ventures
Management Ltd.

[Signature Page to Share Purchase Agreement]

[Table of Contents](#)

SHAREHOLDER

DAN WIZNIZER LTD.

By: /s/ Dan Wiznizer

Name: Dan Wiznizer

Title: CEO

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

ORBIMED ISRAEL PARTNERS LIMITED PARTNERSHIP

By: /s/ Nissim Darvish Erez Chimovitz

Name: Nissim Darvish Erez Chimovitz

Title: Senior Managing Director

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

PONTIFAX (ISRAEL) III LIMITED PARTNERSHIP

By: /s/ Tomer Kariv

Name: Tomer Kariv

Title:

[Signature Page to Share Purchase Agreement]

[Table of Contents](#)

SHAREHOLDER

PONTIFAX (CAYMAN) III LIMITED PARTNERSHIP

By: /s/ Tomer Kariv

Name: Tomer Kariv

Title:

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Dr. Gadi Riesenfeld
Dr. Gadi Riesenfeld

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Yosef Krespi
Yosef Krespi

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Yosef and Lusi Krespi
Yosef and Lusi Krespi

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Lisandro Yelin
Lisandro Yelin

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Dr. Eran Eilat
Dr. Eran Eilat

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Anat Nursella
Chen Schor (by proxy)

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

OTODYNE INC. (by proxy)

By: /s/ Gregory J. Flesher

Name: Gregory J. Flesher

Title: Chief Executive Officer

[Signature Page to Share Purchase Agreement]

SHAREHOLDER

/s/ Anat Nursella

Rodrigo Yelin (by proxy)

[Signature Page to Share Purchase Agreement]

ANNEX B: FORM OF TOKAI STOCK PURCHASE AGREEMENT

STOCK PURCHASE AGREEMENT

This Stock Purchase Agreement (“Agreement”) is made as of [] [], 201[] (the “Effective Date”), by and among Tokai Pharmaceuticals, Inc., a Delaware corporation (the “Company”), each of those persons and entities, severally and not jointly, listed as a Purchaser on the Schedule of Purchasers attached as Exhibit A hereto (the “Schedule of Purchasers”). The persons and entities listed as Purchasers on the Schedule of Purchasers are hereinafter collectively referred to herein as “Purchasers” and each individually as a “Purchaser.”

BACKGROUND

A. On December , 2016, the Company entered into a Share Purchase Agreement with Otic Pharma, Ltd. (“Otic”) and its shareholders (as amended from time to time, the “Otic Share Purchase Agreement”), pursuant to which the Company has agreed to issue shares of its Common Stock (the “Otic Acquisition Shares”) to the shareholders of Otic in consideration for the acquisition of 100% of the issued and outstanding capital stock of Otic, whereupon Otic will become a wholly-owned subsidiary of the Company (the “Otic Acquisition”).

B. The closing of the transactions contemplated under the Otic Share Purchase Agreement is conditioned upon, among other things, the approval of the issuance of the Otic Acquisition Shares by the stockholders of the Company at a special meeting of stockholders.

C. The Company is entering into this Agreement with the Purchasers to provide for the offering and sale of Common Stock, conditioned upon, and subject to, the closing of the Otic Acquisition under the Otic Share Purchase Agreement.

AGREEMENT

In consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Company, and each Purchaser (severally and not jointly) hereby agree as follows:

1. AUTHORIZATION OF SALE OF THE SHARES.

The Company has authorized the sale and issuance of shares of its Common Stock, par value \$0.0001 per share (the “Common Stock”), on the terms and subject to the conditions set forth in this Agreement. The shares of Common Stock sold hereunder at the Closing (as defined below) shall be referred to as the “Shares.”

2. AGREEMENT TO SELL AND PURCHASE THE SHARES.

(a) **Sale of Shares.** At the Closing (as defined in Section 3), the Company will sell to each Purchaser, and each Purchaser will purchase from the Company, the number of Shares set forth opposite such Purchaser’s name on the Schedule of Purchasers at a purchase price of \$1.11 per Share (subject to appropriate adjustment for stock splits, stock dividends, recapitalizations and similar transactions affecting the Common Stock). The aggregate purchase price for the Shares purchased by each Purchaser is set forth opposite such Purchaser’s name on the Schedule of Purchasers.

(b) **Separate Agreement.** Each Purchaser shall severally, and not jointly, be liable for only the purchase of the Shares that appear on the Schedule of Purchasers that relate to such Purchaser. The Company’s agreement with each of the Purchasers, is a separate agreement, and the sale of Shares to each of the Purchasers is a separate sale. The obligations of each Purchaser hereunder are expressly not conditioned on the purchase by any or all of the other Purchasers of the Shares such other Purchasers have agreed to purchase.

[Table of Contents](#)

3. CLOSING AND DELIVERY.

(a) **Closing.** The closing of the purchase and sale of the Shares (which Shares are set forth in the Schedule of Purchasers) pursuant to this Agreement (the “Closing”) shall be held immediately following the satisfaction or waiver of the closing conditions set forth in Sections 6 and 7, including the closing of the Otic Acquisition, with the Closing to occur at the offices of the Company, or on such other date and at such other place as may be agreed to by the Company and the Purchasers (the “Closing Date”). At or prior to the Closing, each Purchaser shall execute any related agreements or other documents required to be executed hereunder, dated on or before the Closing Date.

(b) **Issuance of the Shares at the Closing.** At the Closing, the Company shall issue or deliver to each Purchaser evidence of a book entry position evidencing the Shares purchased by such Purchaser hereunder, registered in the name of such Purchaser, or in such nominee name(s) as designated by such Purchaser, representing the number of Shares to be purchased by such Purchaser at such Closing as set forth in the Schedule of Purchasers against payment of the purchase price for such Shares. The name(s) in which the Shares are to be issued to each Purchaser are set forth in the Purchaser Questionnaire and the Selling Stockholder Notice and Questionnaire in the form attached hereto as Appendices I and II (the “Purchaser Questionnaire” and the “Selling Stockholder Questionnaire,” respectively), as completed by each Purchaser. The Purchaser Questionnaire shall be provided to the Company in connection with the execution of this Agreement and the Selling Stockholder Questionnaire shall be provided to the Company no later than the Closing Date.

(c) **Delivery of the Registration Rights Agreement.** At or before the Closing, the Company and each Purchaser shall execute and deliver the Registration Rights Agreement in the form attached hereto as Appendix III (the “Registration Rights Agreement”), with respect to the registration of the Shares under the Securities Act of 1933, as amended (the “Securities Act”).

4. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY.

Except as set forth on the Schedule of Exceptions delivered to the Purchasers concurrently with the execution of this Agreement (the “Schedule of Exceptions”) or as otherwise described in the SEC Documents (as defined below), which disclosures qualify these representations and warranties in their entirety, the Company hereby represents and warrants as of the date hereof, and covenants with, the Purchasers as follows:

(a) **Organization and Standing.** The Company: (a) has been duly incorporated and is validly existing as a corporation in good standing under the laws of Delaware with full corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as presently conducted, and (b) is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction which requires such qualification, except in the case of clause (b) above, to the extent that the failure to be so qualified or be in good standing would not reasonably be expected to result in (i) a material adverse effect on the validity or enforceability of this Agreement, (ii) a material adverse effect on the condition (financial or otherwise), earnings, business or properties of the Company, or (iii) a material adverse effect on the Company’s ability to perform in any material respect its obligations under this Agreement (any of clauses (i), (ii) or (iii), a “Material Adverse Effect”). The Company has no subsidiaries.

(b) **Corporate Power; Authorization.** The Company has all requisite corporate power and authority, and has taken all requisite corporate action, to execute and deliver this Agreement and the Registration Rights Agreement (as defined below, and together with the Agreement, the “Transaction Documents”), and, subject to any required stockholder approval under the rules and regulations of NASDAQ, to sell and issue the Shares and carry out and perform all of its obligations under the Transaction Documents. Each Transaction Document constitutes the legal, valid and binding obligation of the Company, enforceable in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting the enforcement of creditors’ rights generally, (ii) as limited by equitable principles generally,

[Table of Contents](#)

including any specific performance and (iii) with respect to the Registration Rights Agreement, as rights to indemnity or contribution may be limited by state or federal laws or public policy underlying such laws.

(c) **Issuance and Delivery of the Shares.** The Shares have been duly authorized and, when issued and paid for in compliance with the provisions of this Agreement, will be validly issued, fully paid and non-assessable and free of any security interest, lien, pledge, claim, charge, escrow, encumbrance, right of first offer, right of first refusal, preemptive right, mortgage, indenture, security agreement or other restriction (“**Encumbrance**”) other than restrictions on transfer under the Transaction Documents, applicable state and federal securities laws and Encumbrances created by or imposed by the Purchasers. Assuming the accuracy of the representations made by each Purchaser in [Section 5](#), the offer and issuance by the Company of the Shares is exempt from registration under the Securities Act.

(d) **SEC Documents; Financial Statements.** The Company has filed in a timely manner all documents that the Company was required to file with the Securities and Exchange Commission (the “**Commission**”) under Sections 13, 14(a) and 15(d) the Securities [Exchange Act](#) of 1934, as amended (the “**Exchange Act**”), since becoming subject to the requirements of the Exchange Act. As of their respective filing dates (or, if amended prior to the date of this Agreement, when amended), all documents filed by the Company with the Commission since January 1, 2016 (the “**SEC Documents**”) complied in all material respects with the requirements of the Exchange Act and the rules and regulations of the Commission promulgated thereunder. None of the SEC Documents as of their respective dates contained any untrue statement of material fact or omitted to state a material fact required to be stated therein or necessary to make the statements made therein, in light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Documents (the “**Financial Statements**”) present fairly the financial condition, results of operations and cash flows of the Company as of the dates and for the periods indicated, comply as to form with the applicable accounting requirements of the Exchange Act and have been prepared in conformity with United States generally accepted accounting principles applied on a consistent basis throughout the periods involved (except as otherwise noted therein). PricewaterhouseCoopers LLP, who have certified certain financial statements of the Company delivered their report with respect to the audited financial statements and schedules included in the SEC Documents, are independent public accountants with respect to the Company within the meaning of Regulation S-X.

(e) **Capitalization.** The authorized capital stock of the Company is as set forth in the SEC Documents. As of the Effective Date, there are no shares of Preferred Stock issued and outstanding and there are [] shares of Common Stock issued and outstanding, of which no shares are owned by the Company. There are no other shares of any other class or series of capital stock of the Company issued or outstanding. The Company has no capital stock reserved for issuance, except that, as of the Effective Date, there are (i) [] shares of Common Stock reserved for issuance pursuant to the Company’s stock incentive plans, of which [] shares are issuable upon the exercise of stock options outstanding on the date hereof and [] shares are issuable upon the vesting of restricted stock units outstanding on the date hereof, (ii) [] shares of Common Stock reserved for issuance pursuant to the Company’s employee stock purchase plan and (iii) [] shares of Common Stock reserved for issuance upon the exercise of outstanding warrants. There are no bonds, debentures, notes or other indebtedness having general voting rights (or convertible into securities having such rights) (“**Voting Debt**”) of the Company issued and outstanding. Except as stated above, and except for the obligations to issue the Otic Acquisition Shares under the Otic Share Purchase Agreement, there are no existing options, warrants, calls, subscriptions or other rights, agreements, arrangements or commitments relating to the issued or unissued capital stock of the Company, obligating the Company to issue, transfer, sell, redeem, purchase, repurchase or otherwise acquire or cause to be issued, transferred, sold, redeemed, purchased, repurchased or otherwise acquired any capital stock or Voting Debt of, or other equity interest in, the Company or securities or rights convertible into or exchangeable for such shares or equity interests or obligations of the Company to grant, extend or enter into any such option, warrant, call, subscription or other right, agreement, arrangement or commitment. The issuance of Common Stock or other securities pursuant to any provision of this Agreement will not give rise to any preemptive rights or rights of first refusal on behalf of any natural person or legal entity (each

[Table of Contents](#)

a “**Person**”) or result in the triggering of any anti-dilution rights. There are no agreements or arrangements under which the Company is obligated to register the sale of any of its securities under the Securities Act.

(f) **Litigation.** No action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its property is pending or, to the best knowledge of the Company, threatened that will have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

(g) **Governmental Consents.** No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state, or local governmental authority on the part of the Company is required in connection with the consummation of the transactions contemplated by this Agreement or the Registration Rights Agreement except for (a) the approval by the NASDAQ Stock Market of the listing of the Shares and (b) the filing of one or more registration statements and all amendments thereto with the Commission as contemplated by the Registration Rights Agreement.

(h) **No Default or Consents.** Neither the execution, delivery or performance of the Transaction Documents by the Company nor the consummation of any of the transactions contemplated thereby (including, without limitation, the issuance and sale by the Company of the Shares) will conflict with, result in a breach or violation of, or imposition of any lien, charge or Encumbrance upon any property or assets of the Company pursuant to, (i) the certificate of incorporation or by-laws of the Company, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which the Company is a party or bound or to which its or their property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree applicable to the Company of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any of its properties, except in the case of clauses (ii) and (iii) above, for any conflict, breach or violation of, or imposition that would not have a Material Adverse Effect.

(i) **No Material Adverse Change.** Since September 30, 2016, there have not been any material adverse changes in the assets, liabilities, financial condition, business or operations of the Company from that reflected in the Financial Statements except for the continued incurrence of losses and changes in the ordinary course of business which have not had, either individually or in the aggregate, a Material Adverse Effect.

(j) **No General Solicitation.** Neither the Company nor any Person acting on its behalf, has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D promulgated under the Securities Act) in connection with the offer or sale of the Shares.

(k) **No Integrated Offering.** Neither of the Company or any Person acting on its behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any Company security, under circumstances that would adversely affect reliance by the Company on Section 4(a)(2) of the Securities Act or require registration of any of the Shares under the Securities Act or cause this offering of the Shares to be integrated with prior offerings by the Company for purposes of the Securities Act.

(l) **Sarbanes-Oxley Act.** There is and has been no failure on the part of the Company and any of the Company’s directors or officers, in their capacities as such, to comply in any material respect with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including, without limitation, Section 402 relating to loans.

(m) **Intellectual Property.** The Company owns, possesses, licenses or has other rights to use, on reasonable terms, all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, know-how and other intellectual property (collectively, the “**Intellectual Property**”) that it uses in the conduct of the Company’s business (the “**Company Intellectual Property**”). To the knowledge of the Company, there are no rights of third parties to any Company

[Table of Contents](#)

Intellectual Property, other than as licensed by the Company. To the knowledge of the Company, there is no infringement by third parties of any Company Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any Company Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any Company Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary rights of others. The Company is not aware of any facts required to be disclosed to the U.S. Patent and Trademark Office ("USPTO") which have not been disclosed to the USPTO and which would preclude the grant of a patent in connection with any patent application of the Company Intellectual Property or would form the basis of a finding of invalidity with respect to any issued patents of the Company Intellectual Property that would have a Material Adverse Effect.

(n) **Compliance with NASDAQ Continued Listing Requirements.** The Company is in compliance with applicable NASDAQ continued listing requirements. There are no proceedings pending or, to the Company's knowledge, threatened against the Company relating to the continued listing of the Common Stock on NASDAQ and the Company has not received any notice of, nor to the Company's knowledge is there any reasonable basis for, the delisting of the Common Stock from NASDAQ.

(o) **Disclosure.** The Company understands and confirms that the Purchasers will rely on the foregoing representations in effecting transactions in securities of the Company.

(p) **Contracts.** Each franchise, contract or other document of a character required to be described in the SEC Documents or to be filed as an exhibit to the SEC Documents under the Securities Act and the rules and regulations promulgated thereunder is so described or filed.

(q) **Properties and Assets.** The Company holds all the properties it owns free from liens and encumbrances and leases all properties leased by it under valid and enforceable leases, except as such would not have a Material Adverse Effect.

(r) **Compliance.** Except as would not result in a Material Adverse Effect: (i) the Company is and has been in compliance with statutes, laws, ordinances, rules and regulations applicable to the Company for the ownership, testing, development, manufacture, packaging, processing, use, labeling, storage, or disposal of any product manufactured by or on behalf of the Company or out-licensed by the Company (a "Company Product"), including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., the Public Health Service Act, 42 U.S.C. § 262, similar laws of other governmental entities and the regulations promulgated pursuant to such laws (collectively, "Applicable Laws"); (ii) the Company possesses all licenses, certificates, approvals, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws and/or for the ownership of its properties or the conduct of its business as it relates to a Company Product and as described in the SEC Documents (collectively, "Authorizations") and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iii) the Company has not received any written notice of adverse finding, warning letter or other written correspondence or notice from the U.S. Food and Drug Administration (the "FDA") or any other governmental entity alleging or asserting noncompliance with any Applicable Laws or Authorizations relating to a Company Product; (iv) the Company has not received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental entity or third party alleging that any Company Product, operation or activity related to a Company Product is in violation of any Applicable Laws or Authorizations or has any knowledge that any such governmental entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, to the Company's knowledge, has there been any noncompliance with or violation of any Applicable Laws by the Company that would reasonably be expected to require the issuance of any such written notice or result in an investigation, corrective action, or enforcement action by the FDA or similar governmental entity with respect to a Company Product; (v) the

[Table of Contents](#)

Company has not received written notice that any governmental entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such governmental entity has threatened or is considering such action with respect to a Company Product; and (vi) the Company has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission). To the Company's knowledge, neither the Company nor any of its directors, officers, employees or agents, has made, or caused the making of, any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other governmental entity.

(s) **Taxes.** The Company has filed all tax returns that are required to be filed or has requested extensions thereof (except in any case in which the failure so to file would not have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business) and has paid all taxes required to be paid by it and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing is due and payable, except for any such assessment, fine or penalty that is currently being contested in good faith or as would not have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

(t) **Transfer Taxes.** There are no transfer taxes or other similar fees or charges under Federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance by the Company or sale by the Company of the Shares to the Purchasers.

(u) **Investment Company.** The Company is not, and, immediately after giving effect to the offering and sale of the Shares, will not be, an "investment company" as defined in the Investment Company Act of 1940, as amended.

(v) **Insurance.** The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are reasonable and customary in the business in which it is engaged; all policies of insurance and fidelity or surety bonds insuring the Company or its businesses, assets, employees, officers and directors are in full force and effect; the Company is in compliance with the terms of such policies and instruments in all material respects; and there are no claims by the Company under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; the Company has not been refused any insurance coverage sought or applied for; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

(w) **Price of Common Stock.** The Company has not taken, directly or indirectly, any action designed to cause or result in, or that has constituted or that would reasonably be expected to constitute the stabilization or manipulation of the price of any securities of the Company to facilitate the sale or resale of the Shares.

(x) **Governmental Permits, Etc.** The Company possesses all licenses, certificates, permits and other authorizations issued by all applicable authorities necessary to conduct its business, and the Company has not received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which failure to possess or proceedings, singly or in the aggregate, would have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

(y) **Internal Control over Financial Reporting; Sarbanes-Oxley Matters.** The Company maintains a system of internal accounting controls which are designed to provide reasonable assurance that (i) transactions

[Table of Contents](#)

are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company's internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and the Company is not aware of any material weakness in its internal controls over financial reporting. The Company maintains "disclosure controls and procedures" (as such term is defined in Rule 13a-15(e) under the Exchange Act).

(z) **Foreign Corrupt Practices.** The Company has not nor, to the knowledge of the Company, has any director, officer, agent, or employee of the Company taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "**FCPA**"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA; and the Company.

(aa) **Labor.** No labor problem or dispute with the employees of the Company exists or, to the knowledge of the Company, is threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors, that would have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

(bb) **ERISA.** None of the following events has occurred or exists: (i) a failure to fulfill the obligations, if any, under the minimum funding standards of Section 302 of the United States Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"), and the regulations and published interpretations thereunder with respect to a Plan that is required to be funded, determined without regard to any waiver of such obligations or extension of any amortization period; (ii) an audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other federal or state governmental agency or any foreign regulatory agency with respect to the employment or compensation of employees by any of the Company that could have a Material Adverse Effect; (iii) any breach of any contractual obligation, or any violation of law or applicable qualification standards, with respect to the employment or compensation of employees by the Company that would reasonably be expected to have a Material Adverse Effect. None of the following events has occurred or is reasonably likely to occur: (i) a material increase in the aggregate amount of contributions required to be made to all Plans in the current fiscal year of the Company compared to the amount of such contributions made in the most recently completed fiscal year of the Company except as a result of the Otic Acquisition; (ii) a material increase in the "accumulated post-retirement benefit obligations" (within the meaning of Statement of Financial Accounting Standards 106) of the Company compared to the amount of such obligations in the most recently completed fiscal year of the Company; (iii) any event or condition giving rise to a liability under Title IV of ERISA that could have a Material Adverse Effect; or (iv) the filing of a claim by one or more employees or former employees of the Company related to their employment that could have a Material Adverse Effect. For purposes of this paragraph, the term "Plan" means a plan (within the meaning of Section 3(3) of ERISA) subject to Title IV of ERISA with respect to which the Company may have any liability.

(cc) **Environmental Laws.** The Company (i) is in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) has received and is in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its business and (iii) has not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive

[Table of Contents](#)

required permits, licenses or other approvals, or liability would not, individually or in the aggregate, have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business. The Company has not been named as a “potentially responsible party” under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(dd) **Money Laundering Laws.** The operations of the Company are and have been conducted at all times in compliance in all material respects with applicable money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “Money Laundering Laws”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(ee) **OFAC.** Neither the Company nor, to the knowledge of the Company, any director, officer, agent or employee of the Company (i) is currently subject to any sanctions administered or imposed by the United States (including any administered or enforced by the Office of Foreign Assets Control of the U.S. Treasury Department, the U.S. Department of State, or the Bureau of Industry and Security of the U.S. Department of Commerce), the United Nations Security Council, the European Union, or the United Kingdom (including sanctions administered or controlled by Her Majesty’s Treasury) (such sanctions, collectively, “Sanctions”) and such persons, collectively, “Sanction Persons”) or (ii) will, directly or indirectly, use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person in any manner that will result in a violation of any economic Sanctions by, or could result in the imposition of Sanctions against, any person (including any person participating in the offering, whether as underwriter, advisor, Purchaser or otherwise). Neither the Company nor, to the knowledge of the Company, any director, officer, agent, or employee of the Company is a person that is, or is 50% or more owned or otherwise controlled by a person that is: (x) the subject of any Sanctions; or (y) located, organized or resident in a country or territory that is, or whose government is, the subject of Sanctions that broadly prohibit dealings with that country or territory (currently, Cuba, Iran, North Korea, Sudan, and Syria) (collectively, “Sanctioned Countries” and each, a “Sanctioned Country”). Except as has been disclosed to the Purchasers, or is not material to the analysis under any Sanctions, the Company has not engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country, in the preceding three years, nor does the Company have any plans to increase its dealings or transactions with Sanctioned Persons or with or in Sanctioned Countries.

(ff) **Compliance in Clinical Trials.** The clinical studies and tests conducted by the Company or on behalf of the Company, have been and, if still pending, are being conducted in all material respects pursuant to all Applicable Laws and Authorizations; the descriptions of the results of such clinical studies and tests contained in the SEC Documents are accurate in all material respects; the Company is not aware of any clinical studies or tests, the results of which the Company believes reasonably call into question the research, nonclinical or clinical study or test results described or referred to in the SEC Documents when viewed in the context in which such results are described; and the Company has not received any written notices or correspondence from any governmental entity requiring the termination, suspension or material modification of any clinical study or test conducted by or on behalf of the Company.

5. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE PURCHASERS.

(a) Each Purchaser, severally and not jointly, represents and warrants to and covenants with the Company that:

i. Such Purchaser (if an entity) is a validly existing corporation, limited partnership or limited liability company and has all requisite corporate, partnership or limited liability company power and authority to enter into and consummate the transactions contemplated by the Transaction Documents and to carry out its obligations hereunder and thereunder, and to invest in the Shares pursuant to this Agreement.

[Table of Contents](#)

ii. Such Purchaser acknowledges that it can bear the economic risk and complete loss of its investment in the Shares and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment contemplated hereby.

iii. Such Purchaser has had an opportunity to receive, review and understand all information related to the Company requested by it and to ask questions of and receive answers from the Company regarding the Company, its business and the terms and conditions of the offering of the Shares, and has conducted and completed its own independent due diligence. Such Purchaser acknowledges that the Company has made available the SEC Documents. Based on the information such Purchaser has deemed appropriate, and without reliance upon any placement agent, it has independently made its own analysis and decision to enter into the Transaction Documents. Such Purchaser is relying exclusively on its own sources of information, investment analysis and due diligence (including professional advice it deems appropriate) with respect to the execution, delivery and performance of the Transaction Documents, the Shares and the business, condition (financial and otherwise), management, operations, properties and prospects of the Company, including but not limited to all business, legal, regulatory, accounting, credit and tax matters.

iv. The Shares to be received by such Purchaser hereunder will be acquired for such Purchaser's own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the Securities Act.

v. Such Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the Securities Act without prejudice, however, to such Purchaser's right at all times to sell or otherwise dispose of all or any part of such Shares in compliance with applicable federal and state securities laws.

vi. Such Purchaser is not a broker-dealer registered with the Commission under the Exchange Act or an entity engaged in a business that would require it to be so registered, nor is the Purchaser affiliated with a registered broker dealer. Such Purchaser is not party to any agreement for distribution of any of the Shares.

vii. Such Purchaser understands that the Shares are characterized as "restricted securities" under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. Purchaser will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the securities purchased hereunder except in compliance with the Securities Act, applicable blue sky laws, and the rules and regulations promulgated thereunder.

viii. Such Purchaser is an "accredited investor" within the meaning of Rule 501(a) under the Securities Act.

ix. Such Purchaser has determined based on its own independent review and such professional advice as it deems appropriate that its purchase of the Shares and participation in the transactions contemplated by the Transaction Documents (i) are fully consistent with its financial needs, objectives and condition, (ii) comply and are fully consistent with all investment policies, guidelines and other restrictions applicable to such Purchaser, (iii) have been duly authorized and approved by all necessary action, (iv) do not and will not violate or constitute a default under such Purchaser's charter, by-laws or other constituent document or under any law, rule, regulation, agreement or other obligation by which such Purchaser is bound and (v) are a fit, proper and suitable investment for such Purchaser, notwithstanding the substantial risks inherent in investing in or holding the Shares.

x. The execution, delivery and performance by such Purchaser of the Transaction Documents to which such Purchaser is a party have been duly authorized and each has been duly executed and when delivered

Table of Contents

will constitute the valid and legally binding obligation of such Purchaser, enforceable against such Purchaser in accordance with their respective terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability, relating to or affecting creditors' rights generally.

xi. Such Purchaser shall have completed or caused to be completed and delivered to the Company at no later than the Closing Date, the Purchaser Questionnaire and the Selling Stockholder Questionnaire for use in preparation of the registration statement meeting the requirements set forth in the Registration Rights Agreement and covering the resale by the Purchasers of the Registrable Securities (as defined in the Registration Rights Agreement) (the "Registration Statement"), and the answers to the Purchaser Questionnaire and the Selling Stockholder Questionnaire are true and correct as of the date of this Agreement and will be true and correct as of the Closing and the effective date of the Registration Statement; provided, that the Purchasers shall be entitled to update the information in the Selling Stockholder Questionnaire by providing notice thereof to the Company before the effective date of such Registration Statement.

xii. Such Purchaser understands that no United States federal or state agency, or similar agency of any other country, has reviewed, approved, passed upon, or made any recommendation or endorsement of the Company or the purchase of the Shares.

xiii. Such Purchaser has no present intent to effect a "change of control" of the Company as such term is understood under the rules promulgated pursuant to Section 13(d) of the Exchange Act.

xiv. Such Purchaser has not taken any of the actions set forth in, and is not subject to, the disqualification provisions of Rule 506(d)(1) of the Securities Act.

xv. Such Purchaser did not learn of the investment in the Shares as a result of any general solicitation or general advertising.

xvi. Such Purchaser's residence (if an individual) or offices in which its investment decision with respect to the Shares was made (if an entity) are located at the address immediately below such Purchaser's name on its signature page hereto.

xvii. Such Purchaser (including any person controlling, controlled by, or under common control with such Purchaser, as the term "control" is defined pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and its implementing regulations (the "HSR Act")) in connection with the consummation of the transactions contemplated by this Agreement will not be required to and will not complete a filing with the U.S. government pursuant to the HSR Act.

(b) Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include the location and/or reservation of borrowable shares of Common Stock) ("Short Sales"), of the securities of the Company during the period commencing as of the time that such Purchaser was first contacted by the Company or any other person regarding the transactions contemplated hereby and ending immediately prior to the Effective Date. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Shares covered by this Agreement. Other than to other persons party to this Agreement, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or

[Table of Contents](#)

preclude any actions, with respect to the identification of the availability of, or securing of, available shares to borrow in order to effect Short Sales or similar transactions in the future.

(c) Purchaser understands that nothing in this Agreement or any other materials presented to Purchaser in connection with the purchase and sale of the Shares constitutes legal, tax or investment advice. Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Shares.

(d) Legends.

(a) Purchaser understands that, until such time as the Shares have been sold pursuant to the Registration Statement or the Shares may be sold pursuant to Rule 144 under the Securities Act ("Rule 144") without any restriction as to the number of securities as of a particular date that can then be immediately sold, the book entry notations evidencing the Shares may bear one or more legends in substantially the following form and substance:

"THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE REOFFERED, SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCUMBERED, HYPOTHECATED OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO A TRANSACTION WHICH IS EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, IN EACH CASE IN ACCORDANCE WITH ALL APPLICABLE SECURITIES LAWS, AND IN THE CASE OF A TRANSACTION EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO IT THAT SUCH TRANSACTION DOES NOT REQUIRE REGISTRATION UNDER THE SECURITIES ACT AND SUCH OTHER APPLICABLE LAWS."

In addition, book entry notations representing the Shares may contain:

- (i) Any legend required by the laws of the State of California, including any legend required by the California Department of Corporations.
- (ii) Any legend required by the blue sky laws of any other state to the extent such laws are applicable to the sale of such Shares hereunder.
- (iii) A legend regarding affiliate status of the Purchasers set forth in Schedule 1 hereto, in the form included therein.

(b) The Company agrees that at such time as such legend is no longer required under this section, it will, no later than three business days following the delivery by a Purchaser to the Company or the Company's transfer agent of a certificate representing Shares, and if such Shares are certificated, issued with a restrictive legend, together with such representations and covenants of such Purchaser or such Purchaser's executing broker as the Company may reasonably require in connection therewith, deliver or cause to be delivered to such Purchaser a book entry position representing such shares that is free from any legend referring to the Securities Act. The Company shall not make any notation on its records or give instructions to any transfer agent of the Company that enlarge the restrictions on transfer set forth in this section. To the extent that certificates or book entry positions are issued representing the Shares, such certificates or book entry positions subject to legend removal hereunder shall be transmitted by the transfer agent of the Company to the Purchasers by crediting the account of such Purchaser's prime broker with the Depository Trust Company ("DTC"). All costs and expenses related to the removal of the legends and the reissuance of any Shares shall be borne by the Company.

[Table of Contents](#)

(c) The restrictive legend set forth in this section above shall be removed and the Company shall issue a certificate or book entry position without such restrictive legend or any other restrictive legend to the holder of the applicable shares upon which it is stamped or issue to such holder by electronic delivery with the applicable balance account at DTC or in physical certificated shares, if appropriate, if (i) such Shares are registered for resale under the Securities Act (provided that, if the Purchaser is selling pursuant to an effective registration statement registering the Shares for resale, the Purchaser agrees to only sell such Shares during such time that such registration statement is effective and such Purchaser is not aware or has not been notified by the Company that such registration statement has been withdrawn or suspended, and only as permitted by such registration statement); (ii) such Shares are sold or transferred pursuant to Rule 144 (if the transferor is not an affiliate of the Company); or (iii) such Shares are eligible for sale without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such securities and without volume or manner-of-sale restrictions. Subject to receipt of such representations, and covenants as are contemplated hereby, following the earlier of (i) the effective date of the Registration Statement or (ii) Rule 144 becoming available for the resale of the Shares, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to the Shares and without volume or manner-of-sale restrictions, the Company shall issue to the Company's transfer agent the instructions with respect to legend removal consistent with this section. Any fees (with respect to the transfer agent, the Company's counsel or otherwise) associated with the issuance of such opinion or the removal of such legend shall be borne by the Company.

(e) **Restricted Shares.** Purchaser understands that the Shares are characterized as "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such Shares may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, such Purchaser represents that it is familiar with Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

(f) **Exculpation Among Purchasers.** Purchaser acknowledges that it is not relying upon any other Purchaser, or any officer, director, employee, agent, partner, member or affiliate of any such other Purchaser, in making its investment or decision to invest in the Company. Purchaser agrees that neither any Purchaser nor the respective controlling Persons, officers, directors, partners, agents, or employees of any Purchaser shall be liable to any other Purchaser for any action heretofore taken or omitted to be taken by any of them in connection with the purchase of the Shares.

6. CONDITIONS TO COMPANY'S OBLIGATIONS AT THE CLOSING.

The Company's obligation to complete the sale and issuance of the Shares and deliver Shares to each Purchaser, individually, as set forth in the Schedule of Purchasers at the Closing shall be subject to the fulfillment of the following conditions to the extent not waived by the Company:

(a) **Receipt of Payment.** The Company shall have received payment, by wire transfer of immediately available funds, in the full amount of the purchase price for the number of Shares being purchased by such Purchaser at the Closing as set forth in the Schedule of Purchasers.

(b) **Representations and Warranties.** The representations and warranties made by the Purchasers in Section 5 hereof shall be true and correct in all material respects when made, and shall be true and correct in all material respects on the Closing Date with the same force and effect as if they had been made on and as of said date.

6.3 **Performance.** The Purchasers shall have performed in all material respects all obligations and covenants herein required to be performed by them on or prior to the Closing Date.

(c) **Receipt of Executed Documents.** Each of the Purchasers shall have executed and delivered to the Company the Registration Rights Agreement, the Purchaser Questionnaire and the Selling Stockholder Questionnaire.

[Table of Contents](#)

(d) **Share Purchase Agreement.** The Company and the other parties thereto shall have executed and delivered to the Purchasers copies of the Share Purchase Agreement.

(e) **Otic Acquisition.** The Otic Acquisition shall have been completed pursuant to the Otic Share Purchase Agreement.

7. CONDITIONS TO PURCHASERS' OBLIGATIONS AT THE CLOSING.

Each Purchaser's obligation to accept delivery of the Shares and to pay for the Shares shall be subject to the fulfillment of the following conditions to the extent not waived by such Purchaser:

(a) **Performance.** The Company shall have performed in all material respects all obligations and covenants herein required to be performed by it on or prior to the Closing Date.

(b) **Receipt of Executed Registration Rights Agreement.** The Company shall have executed and delivered to the Purchasers the Registration Rights Agreement.

(c) **Legal Opinion.** The Purchasers shall have received an opinion, dated as of the Closing Date, in form and substance reasonably acceptable to the Purchasers.

(d) **Certificate.** Each Purchaser shall have received a certificate signed by the Chief Executive Officer or the Chief Financial Officer to the effect the Company has satisfied in all material respects all of the conditions set forth in this [Section 7](#).

(e) **Good Standing.** The Company is validly existing as a corporation in good standing under the laws of Delaware.

(f) **Nasdaq Approval.** The Company shall have filed with NASDAQ a Notification Form: Listing of Additional Shares for the listing of the Shares, and, if required, shall have obtained stockholder approval of the issuance of the Shares hereunder

(g) **Judgments.** No judgment, writ, order, injunction, award or decree of or by any court, or judge, justice or magistrate, including any bankruptcy court or judge, or any order of or by any governmental authority, shall have been issued, and no action or proceeding shall have been instituted by any governmental authority, enjoining or preventing the consummation of the transactions contemplated hereby.

(h) **Share Purchase Agreement.** The Company shall have executed and delivered to the Purchasers copies of the Share Purchase Agreement.

(i) **Stop Orders.** No stop order or suspension of trading shall have been imposed by the NASDAQ Stock Market, the Commission or any other governmental regulatory body with respect to public trading in the Common Stock (any such order or suspension, a "[Suspension](#)").

(j) **Otic Acquisition.** The Otic Acquisition shall have been completed pursuant to the Otic Share Purchase Agreement.

8. TERMINATION OF OBLIGATIONS TO EFFECT CLOSING; EFFECTS.

(a) This Agreement may be terminated, on a Purchaser-by-Purchaser basis, as follows:

i. upon the mutual written consent of the Company and such Purchaser;

ii. by the Company if any of the conditions set forth in [Sections 6](#) shall have become incapable of fulfillment, and shall not have been waived by the Company or satisfied by _____, 2017; or

[Table of Contents](#)

iii. by such Purchaser if the Otic Share Purchase Agreement shall have been terminated without the Company having consummated the Otic Acquisition;

Provided, however, that, except in the case of clause (b) above, the party seeking to terminate its obligation to effect the Closing shall not then be in breach of any of its representations, warranties, covenants or agreements contained in this Agreement or the other Transaction Documents if such breach has resulted in the circumstances giving rise to such party's seeking to terminate its obligation to effect the Closing.

(b) If this Agreement is terminated by either the Company or a Purchaser pursuant to the provisions of Section 8(a), this Agreement with respect to the Company and such Purchaser shall forthwith become void and there shall be no further obligations or liability on the part of the Company or such Purchaser or their respective stockholders, directors, officers, employees, agents or representatives, except for the provisions of Sections 10.4 with respect to the Confidentiality Obligations (as defined below), 12 and 13, which shall survive any termination of this Agreement; provided, that nothing in this Section 8 shall be deemed (i) to release any party from any liability for any knowing or intentional breach by such party of the terms and provisions of this Agreement or the other Transaction Documents, or (ii) to impair the right of any party to compel specific performance by any other party of its obligations under this Agreement or the other Transaction Documents, in either case, which may have arisen prior to termination of this Agreement.

9. BROKER'S FEES.

The Company and each Purchaser (severally and not jointly) hereby represent that there are no other brokers or finders entitled to compensation, commissions, placement agent's fees or similar payments in connection with the sale of the Shares, and shall indemnify each other for any such fees for which they are responsible.

10. ADDITIONAL AGREEMENTS OF THE PARTIES.

(a) **NASDAQ Listing.** The Company will use commercially reasonable efforts to continue the listing and trading of its Common Stock on NASDAQ and, in accordance, therewith, will use commercially reasonable efforts to comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of such market or exchange, as applicable.

(b) **Termination of Covenants.** The provisions of Section 10.1 shall terminate and be of no further force and effect on the date on which the Company's obligations under the Registration Rights Agreement to register or maintain the effectiveness of any registration covering the Registrable Securities (as such term is defined in the Registration Rights Agreement) shall terminate.

(c) **Integration.** The Company shall not, and shall use its commercially reasonable efforts to ensure that no affiliate of the Company shall, sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that will be integrated with the offer or sale of the Shares in a manner that would require the registration under the Securities Act of the sale of the Shares to the Purchasers, or that will be integrated with the offer or sale of the Shares for purposes of the rules and regulations of any trading market such that it would require stockholder approval prior to the closing of such other transaction unless stockholder approval is obtained before the closing of such subsequent transaction.

(d) **Short Sales and Confidentiality After the Date Hereof.** Each Purchaser covenants that neither it nor any affiliates acting on its behalf or pursuant to any understanding with it will execute any Short Sales during the period from the date hereof until the earlier of such time as (i) after the transactions contemplated by this Agreement are first publicly announced or (ii) this Agreement is terminated in full. Except (x) as required by applicable law or the listing rules of any applicable national or regional securities exchange, (y) as required to be disclosed in filings or other submissions to any court, regulatory body, administrative agency, governmental

[Table of Contents](#)

body, arbitrator or other legal authority having jurisdiction over a party hereto made to obtain necessary consents, approvals or filings, or (z) as provided by the terms and provisions of the existing confidentiality and non-use obligations of the parties hereto (including the existence and terms of this transaction) (such obligations, the “Confidentiality Obligations”). Each Purchaser understands and acknowledges that the Commission currently takes the position that coverage of short sales of shares of the Common Stock “against the box” prior to effectiveness of a resale registration statement with securities included in such registration statement would be a violation of Section 5 of the Securities Act, as set forth in Item 239.10 of the Securities Act Rules Compliance and Disclosure Interpretations compiled by the Office of Chief Counsel, Division of Corporation Finance.

(e) **Securities Laws Disclosure; Publicity.** By 5:00 P.M., New York City time, on the second trading day immediately following the Effective Date, the Company shall issue a press release disclosing the material terms of the transactions contemplated hereby. On or before 9:00 A.M., New York City time, on the third trading day immediately following the execution of this Agreement, the Company will file a Current Report on Form 8-K (the “8-K”) with the Commission describing the material terms of the Transaction Documents (and including as exhibits to such Current Report on Form 8-K the agreements required to be filed in connection therewith). Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any public filing with the Commission or any regulatory agency or NASDAQ, without the prior written consent of such Purchaser, which consent shall not be unreasonably withheld, conditioned or delayed, except: (a) as required by federal securities law in connection with (i) any registration statement contemplated by the Registration Rights Agreement, (ii) the filing of a proxy statement seeking stockholder approval of the issuance and sale of the Shares and (iii) the filing of final Transaction Documents with the Commission; and (b) as otherwise required by law or Nasdaq regulations, provided that to the extent disclosure is permitted by law or NASDAQ regulations, the Company shall provide the Purchaser with prior notice of such disclosure under this clause (b). As of the time of the filing of the 8-K, the Company shall not be aware that any Purchaser shall be in possession of any material, non-public information received from the Company, any subsidiary of the Company or any of their respective officers, directors, employees or agents, pursuant to the transactions contemplated by this Agreement that is not disclosed in the 8-K, press release or other disclosure by the Company that complies with the requirements of Regulation FD.

11. INDEMNIFICATION.

(a) **Indemnification by the Company.** The Company agrees to indemnify and hold harmless each of the Purchasers and each Person, if any, who controls any Purchaser within the meaning of the Securities Act (each, an “Indemnified Party”), against any losses, claims, damages, liabilities or expenses, joint or several, to which such Indemnified Party may become subject under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation, or at common law (including in settlement of any litigation, if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) arise out of or are based in whole or in part on the inaccuracy in the representations and warranties of the Company contained in this Agreement or the failure of the Company to perform its obligations hereunder, and will reimburse each Indemnified Party for legal and other expenses reasonably incurred as such expenses are reasonably incurred by such Indemnified Party in connection with investigating, defending, settling, compromising or paying such loss, claim, damage, liability, expense or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage, liability or expense arises out of or is based upon (i) the failure of such Indemnified Party to comply with the covenants and agreements contained in Sections 5 and 4 above respecting sale of the Shares, or (ii) the inaccuracy of any representations made by such Indemnified Party herein.

(b) **Indemnification by Purchasers.** Each Purchaser shall severally, and not jointly, indemnify and hold harmless the other Purchasers and the Company, each of its directors, and each Person, if any, who controls the Company within the meaning of the Securities Act, against any losses, claims, damages, liabilities or expenses to which the Company, each of its directors or each of its controlling Persons may become subject, under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation, or at

[Table of Contents](#)

common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Purchaser) insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) arise out of or are based upon (i) any failure by such Purchaser to comply with the covenants and agreements contained in Sections 5 and 4 above respecting the sale of the Shares unless such failure by such Purchaser is directly caused by the Company's failure to provide written notice of a Suspension to such Purchaser or (ii) the inaccuracy of any representation made by such Purchaser herein, in each case to the extent, and will reimburse the Company, each of its directors, and each of its controlling Persons for any legal and other expense reasonably incurred, as such expenses are reasonably incurred by the Company, each of its directors, and each of its controlling Persons in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. No Purchaser shall be liable for the indemnification obligations of any other Purchaser.

12. NOTICES.

All notices, requests, consents and other communications hereunder shall be in writing, shall be sent by confirmed electronic mail, or mailed by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, and shall be deemed given when so sent in the case of electronic mail transmission, or when so received in the case of mail or courier, and addressed as follows:

if to the Company, to:

Tokai Pharmaceuticals, Inc.
255 State Street, 6th Floor
Boston, MA 02109
Attention: [Chief Executive Officer]
E-Mail:

with copies (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attn: Stuart M. Falber, Esq.
Attn: Hal J. Leibowitz, Esq.

Otic Pharma, Ltd.
Gregory J. Flesher
Chief Executive Officer
19900 MacArthur Blvd., Suite 550
Irvine, California 92612

Gibson, Dunn & Crutcher, LLP
555 Mission Street, Suite 3000
San Francisco, CA 94105
Attn: Ryan A. Murr

or to such other person at such other place as the Company shall designate to the Purchasers in writing; and

if to the Purchasers, at the address as set forth at the end of this Agreement, or at such other address or addresses as may have been furnished to the Company in writing.

13. MISCELLANEOUS.

(a) **Waivers and Amendments.** Neither this Agreement nor any provision hereof may be changed, waived, discharged, terminated, modified or amended with respect to the Company and a Purchaser only with the written consent of the Company and such Purchaser.

[Table of Contents](#)

(b) **Headings.** The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.

(c) **Severability.** In case any provision contained in this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

(d) **Replacement of Shares.** If the Shares are certificated and any certificate or instrument evidencing any Shares is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof, or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company and the Company's transfer agent of such loss, theft or destruction and the execution by the holder thereof of a customary lost certificate affidavit of that fact and an agreement to indemnify and hold harmless the Company and the Company's transfer agent for any losses in connection therewith or, if required by the transfer agent, a bond in such form and amount as is required by the transfer agent. The applicants for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs associated with the issuance of such replacement Shares. If a replacement certificate or instrument evidencing any Shares is requested due to a mutilation thereof, the Company may require delivery of such mutilated certificate or instrument as a condition precedent to any issuance of a replacement.

(e) **Independent Nature of Purchasers' Obligations and Rights.** The obligations of each Purchaser under this Agreement are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser under this Agreement. Nothing contained herein and no action taken by any Purchaser pursuant hereto, shall be deemed to constitute the Purchaser as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group, or are deemed affiliates (as such term is defined under the Exchange Act) with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser shall be entitled to independently protect and enforce its rights, including without limitation the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose.

(f) **Governing Law.** All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the state and federal courts sitting in New York, New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City and County of New York for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law.

(g) **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute but one instrument, and shall

[Table of Contents](#)

become effective when one or more counterparts have been signed by each party hereto and delivered to the other parties. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) the same with the same force and effect as if such facsimile of “.pdf” signature were the original thereof.

(h) **Successors and Assigns.** Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto; provided, however, that a Purchaser may not assign its rights and delegate its duties hereunder in whole or in part to an affiliate or to a third party acquiring some or all of its Shares in a transaction complying with applicable securities laws without the prior written consent of the Company, provided such assignee agrees in writing to be bound by the provisions hereof that apply to Purchasers.

(i) **Entire Agreement.** This Agreement and other documents delivered pursuant hereto, including the exhibit and the Schedule of Exceptions, constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and thereof.

(j) **Payment of Fees and Expenses.** Each of the Company and the Purchasers shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney’s fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

(k) **Survival.** The representations, warranties, covenants and agreements made in this Agreement shall survive any investigation made by the Company or the Purchasers and the Closing.

[signature pages follow]

[Table of Contents](#)

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

TOKAI PHARMACEUTICALS, INC.

By: _____
Name:
Title:

[Table of Contents](#)

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

PURCHASERS:

By: _____

Name: _____

Title: _____

Address: _____

Email: _____

**EXHIBIT A
SCHEDULE OF PURCHASERS**

<u>Name and Address</u>	<u>Number of Shares</u>	<u>Aggregate Purchase Price of Shares</u>
TOTAL		

**APPENDIX I
FORM OF PURCHASER QUESTIONNAIRE**

APPENDIX II
FORM OF SELLING STOCKHOLDER QUESTIONNAIRE

**APPENDIX III
FORM OF REGISTRATION RIGHTS AGREEMENT**

**ANNEX C: FORM OF CERTIFICATE OF AMENDMENT OF THE RESTATED
CERTIFICATE OF INCORPORATION OF TOKAI PHARMACEUTICALS, INC.
(REGARDING THE REVERSE STOCK SPLIT)**

Tokai Pharmaceuticals, Inc. (the “Corporation”), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the “General Corporation Law”), does hereby certify as follows:

1. The current name of the Corporation is Tokai Pharmaceuticals, Inc.

2. The original certificate of incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on March 26, 2004 and was amended and restated on April 27, 2004, May 30, 2007, October 14, 2008, May 6, 2009, November 15, 2010, September 9, 2011 and May 10, 2013, further amended on February 27, 2014, April 17, 2014 and August 29, 2014 and amended and restated on September 22, 2014.

3. The Board of Directors of the Corporation duly adopted resolutions pursuant to Section 242 of the General Corporation Law proposing this Amendment of the Corporation’s Restated Certificate of Incorporation and declaring the advisability of this Amendment of the Restated Certificate of Incorporation and authorizing the appropriate officers of the Corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment is as follows:

RESOLVED, that the first paragraph of Article FOURTH of the Restated Certificate of Incorporation of the Corporation be amended to read in its entirety as follows:

Effective upon the filing of this Certificate of Amendment to the Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the “Effective Time”), a one-for-[] reverse stock split of the Corporation’s common stock, \$0.001 par value per share (the “Common Stock”), shall become effective, pursuant to which each [] shares of Common Stock issued or outstanding (including treasury shares) immediately prior to the Effective Time shall be reclassified and combined into one validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Effective Time and shall represent one share of Common Stock from and after the Effective Time (such reclassification and combination of shares, the “Reverse Stock Split”). The par value of the Common Stock following the Reverse Stock Split shall remain at \$0.001 par value per share. No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split and, in lieu thereof, upon surrender after the Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of the Common Stock immediately prior to the Effective Time as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is 205,000,000 shares, consisting of (i) 200,000,000 shares of Common Stock, \$0.001 par value per share (“Common Stock”), and (ii) 5,000,000 shares of Preferred Stock, \$0.001 par value per share (“Preferred Stock”).

[Table of Contents](#)

4: This Certificate of Amendment of the Restated Certificate of Incorporation has been duly adopted by the stockholders of the Corporation in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment of the Amended and Restated Certificate of Incorporation to be signed by its President and Chief Executive Officer this day of , 2017.

Jodie P. Morrison
President and Chief Executive Officer

ANNEX D: OPINION OF WEDBUSH SECURITIES INC.



Wedbush Securities Inc.
Two Embarcadero Center
Suite 600
San Francisco, CA 94111
December 22, 2016

Board of Directors
Tokai Pharmaceuticals, Inc.
255 State Street, 6th Floor
Boston, MA 02109

Members of the Board:

We understand that Tokai Pharmaceuticals, Inc. (“Tokai”) proposes to enter into a Share Purchase Agreement (the “Purchase Agreement”) by and among Tokai, OticPharma, Ltd. (“Otic”), the shareholders of Otic (each a “Seller” and collectively, the “Sellers”) and the representative of the Sellers, pursuant to which, among other things, the Sellers will sell to Tokai all of the allotted and issued Otic Shares (as defined below) in exchange for the issuance by Tokai to the Sellers of the Tokai Common Stock (as defined below) (the “Transaction”). Capitalized terms used but not defined herein shall have the meanings given to such terms in the Purchase Agreement.

Pursuant to the Purchase Agreement, and as more fully set forth in the Purchase Agreement, each Seller will sell to Tokai all of the ordinary shares, NIS 0.01 nominal value per share, of Otic (“Ordinary Shares”), and preferred shares, NIS 0.01 nominal value per share, of Otic (“Preferred Shares,” together with Ordinary Shares, collectively, “Otic Shares”), owned by such Seller in exchange for the issuance by Tokai to such Seller of the number of shares of Common Stock, \$0.001 par value per share, of Tokai (“Tokai Common Stock”) equal to the portion of the Aggregate Closing Consideration payable to such Seller in accordance with the Otic Pharma Organizational Documents (such number of shares of Tokai Common Stock issued for each such Otic Share, the “Exchange Ratio”). The terms and conditions of the Transaction are set forth in more detail in the Purchase Agreement.

You have asked us whether, in our opinion as investment bankers as of the date hereof, the Exchange Ratio in connection with the Transaction is fair to the stockholders of Tokai from a financial point of view.

Wedbush Securities Inc. (“Wedbush”) is an investment banking firm and member of The New York Stock Exchange and other principal stock exchanges in the United States, and is regularly engaged as part of its business in the valuation of businesses and their securities in connection with mergers and acquisitions, negotiated underwritings, private placements, secondary distributions of listed and unlisted securities, and valuations for corporate, estate and other purposes.

For purposes of this opinion and in connection with our review, we have, among other things: (1) reviewed a draft of the Purchase Agreement dated December 21, 2016, and we have assumed that no changes will be made to the Purchase Agreement that will be material to our analysis; (2) reviewed certain publicly available business and financial information relating to Tokai and Otic, respectively; (3) reviewed certain internal information, primarily financial in nature, including financial and operating data furnished to us by the managements of Tokai and Otic, respectively, and approved for our use by Tokai; (4) reviewed certain publicly available information with respect to other companies in the biopharmaceutical industry that we believe to be

[Table of Contents](#)

similar in certain respects to Otic; (5) considered the financial terms, to the extent publicly available, of selected recent business combinations and initial public offerings of companies in the biopharmaceutical industry that we believe to be similar in certain respects to Otic, in whole or in part, and to the Transaction; and (6) made inquiries regarding and discussed the Purchase Agreement and other matters related thereto with Tokai and Otic counsel. In addition, we have held discussions with the management of Tokai and Otic concerning their views as to the financial and other information described above. In addition to the foregoing, we have conducted such other analyses and examinations and considered such other financial, economic and market criteria as we deem appropriate to arrive at our opinion.

In rendering this opinion, we have relied upon and assumed, without independent verification, the accuracy and completeness of all information that was publicly available or was furnished to or discussed with us by Tokai, Otic or any other party to the Purchase Agreement or otherwise reviewed by us. With respect to information provided to or reviewed by us, we have been advised by the management of Tokai and Otic that such information was reasonably prepared on bases reflecting the best currently available estimates and judgments of the management of Tokai or Otic, as applicable. We express no view as to the reasonableness of such financial information or the assumptions on which it was based.

We have further relied on the assurances of management of Tokai that they are unaware of any facts that would make the information provided to us incomplete or misleading. Except for certain estimates of liabilities expected to be incurred by Tokai in connection with a potential liquidation of Tokai prepared by management of Tokai, we have not made or been provided with any independent evaluations or appraisals of any of the assets, properties, liabilities (including any contingent, derivative or off-balance-sheet assets or liabilities) or securities, nor have we made any physical inspection of the properties or assets, of Tokai or Otic. Further, as you are aware, Otic's management did not provide us with, and we did not otherwise have access to, financial forecasts regarding Otic's business, other than certain operating expense forecasts for the five years ended December 31, 2021, and, accordingly we did not perform either a discounted cash flow analysis or any multiples-based analyses with respect to Otic. With respect to the operating expense forecasts of Otic, upon the advice of Tokai and Otic, we have assumed that such projections have been reasonably prepared on a basis reflecting the best currently available estimates and judgments of the management of Otic as to the future operating expenses of Otic and that Otic will perform substantially in accordance with such projections. We assume no responsibility for and we express no view as to any such projections or the assumptions on which they are based. We did not evaluate the solvency or fair value of Tokai, Otic or any of their respective subsidiaries (or the impact of the transaction thereon) under any law relating to bankruptcy, insolvency or similar matters.

Our opinion is based on economic, market and other conditions as in effect on, and the information made available to us as of, the date hereof. We have also relied on the accuracy and completeness of Tokai's and Otic's representations and warranties in the Purchase Agreement, without regard to any qualifications that may be set forth in disclosure schedules or any other such qualifications. In addition, we have assumed that the Transaction will be consummated in accordance with the terms set forth in the Purchase Agreement without any waiver, amendment or delay of any terms or conditions that would be material to our analysis. Representatives of Tokai have advised us, and we have further assumed that the final terms of the Purchase Agreement will not differ from the terms set forth in the draft we have reviewed in any respect material to our analysis. Events occurring after the date hereof could materially affect the assumptions used in preparing this opinion. We have not undertaken any obligation to reaffirm or revise this opinion or otherwise comment upon any events occurring after the date hereof.

We are not legal, tax or regulatory advisors and do not express any opinion as to any tax or other consequences that may arise from the Transactions, nor does our opinion address any legal, regulatory or accounting matters, as to which we understand that Tokai has obtained such advice as it deemed necessary from qualified professionals. We are financial advisors only and have relied upon, without independent verification, the assessment of Tokai and Otic and their legal, tax or regulatory advisors with respect to legal, tax or regulatory matters. We have assumed that the Transaction will have the tax effects contemplated by the Purchase Agreement.

[Table of Contents](#)

In rendering this opinion, we express no opinion as to the amount or nature of any compensation to any officers, directors, or employees of Tokai, or any class of such persons, whether relative to the Exchange Ratio or otherwise, or with respect to the fairness of any such compensation. We are not opining as to the merits of the Transaction as compared with any alternative transactions or strategies that may be available to Tokai, or as to the likelihood of the consummation of the Transaction. At your direction, we have not been asked to, nor do we, offer any opinion as to the terms, other than the Exchange Ratio to the extent expressly specified herein, of the Purchase Agreement or the form of the Transaction. Nor do we express any opinion with respect to the terms of any other agreement entered into or to be entered into in connection with the Transaction. We express no opinion as to the price at which shares of Tokai Common Stock may trade at any time subsequent to the announcement or consummation of the Transaction. We have also assumed that all governmental, regulatory or other consents and approvals necessary for the consummation of the Transaction will be obtained without imposition of any terms or conditions that would be material to our analysis.

Tokai has agreed to pay Wedbush fees for its services as financial advisor in connection with the Transaction. A portion of such fees becomes payable upon delivery of this opinion and the substantial portion of such fees will become payable upon consummation of the Transaction. In addition, Tokai has agreed to reimburse us for all reasonable out-of-pocket expenses incurred by us and to indemnify us for certain liabilities arising out of our engagement. We may also provide investment banking and financial advisory services to Tokai, Otic and their respective affiliates in the future for which we would expect to receive customary fees.

In the ordinary course of our business, we and our affiliates may actively trade Tokai Common Stock or other instruments or obligations of Tokai for our own account and for the accounts of our customers and, accordingly, we may at any time hold a long or short position in Tokai Common Stock or such instruments or obligations of Tokai.

This opinion is for the benefit and use of the board of directors of Tokai (in its capacity as such) in connection with its evaluation of the Transaction and does not constitute a recommendation to the board of directors of Tokai as to how to act or to any holder of Tokai Common Stock or any other person as to how such holder or other person should vote with respect to the Transaction or any other matter. This opinion may not be used for any other purpose without our prior written consent in each instance, except as expressly provided for in the engagement letter dated as of August 31, 2016 between Tokai and Wedbush.

This opinion was approved by a fairness committee at Wedbush in accordance with the requirements of FINRA Rule 5150.

Based upon and subject to the foregoing, it is our opinion that, as of the date hereof, the Exchange Ratio in connection with the Transaction is fair to the stockholders of Tokai from a financial point of view.

Very truly yours,

/s/ Wedbush Securities Inc.

Wedbush Securities Inc.



SPECIAL MEETING OF TOKAI PHARMACEUTICALS, INC.

Date: ●, ●, 2017
 Time: 9:00 A.M. (Eastern Time)
 Place: 60 State Street, Boston, MA 02109

Please make your marks like this: Use dark black pencil or pen only

Board of Directors Recommends a Vote **FOR** proposals 1, 2 and 3.

1: To approve the issuances of shares of common stock of Tokai, par value \$0.001 per share, pursuant to (i) the terms of the Share Purchase Agreement, dated as of December 21, 2016, by and among Tokai, Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel, and the shareholders of Otic named therein and (ii) the terms of the Tokai Stock Purchase Agreement; dated as of ●, 2017, by and among Tokai, Otic, and the purchasers set forth therein.

For	Against	Abstain
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2: To approve and adopt an amendment to Tokai's Amended and Restated Certificate of Incorporation to effect a reverse stock split of Tokai common stock, at a ratio ranging from ●:1 to ●:1, as determined by the Tokai board of directors and agreed to by Otic.

For	Against	Abstain
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3: To adjourn the special meeting to solicit additional votes to approve the Share Issuances Proposal or the Reverse Stock Split Proposal, if necessary or appropriate.

For	Against	Abstain
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: The proxies are authorized to vote, in their discretion, upon such other business as may properly come before the meeting or any adjournment or postponement thereof.

To attend the meeting and vote your shares in person, please mark this box.

Authorized Signatures - This section must be completed for your Instructions to be executed.

Please Sign Here	Please Date Above
Please Sign Here	Please Date Above

Please sign exactly as your name(s) appears on your stock certificate or book-entry record. If held in joint tenancy, all holders should sign. Trustees, administrators, etc., should include title and authority. Corporations should provide full name of corporation and title of authorized officer signing the proxy.

↑ Please separate carefully at the perforation and return just this portion in the envelope provided. ↑



Special Meeting of Tokai Pharmaceuticals, Inc.

to be held on ●, ●, 2017

for Holders as of [], 2017

This proxy is being solicited on behalf of the Board of Directors

VOTE BY:



INTERNET

Go To

www.proxypush.com/tkai

- Cast your vote online 24 hours a day/7 days a week.
- Have your Proxy Card/Voting Instructions Form ready.
- View Meeting Documents.

OR

- Mark, sign and date your Proxy Card/Voting Instruction Form.
- Detach your Proxy Card/Voting Instruction Form.
- Return your Proxy Card/Voting Instruction Form in the postage-paid envelope provided.



TELEPHONE

Call

(866) 206-4382

- Use any touch-tone telephone toll-free 24 hours a day/7 days a week.
- Have your Proxy Card/Voting Instruction Form ready. Follow the simple recorded instructions.

OR



MAIL

The undersigned hereby appoints Jodie P. Morrison and John S. McBride, and each or any of them, as the true and lawful attorneys of the undersigned, with full power of substitution and revocation, and authorizes them, and any of them, to vote all the shares of capital stock of Tokai Pharmaceuticals, Inc. that the undersigned is entitled to vote at said meeting and any adjournment thereof upon the matters specified and upon such other matters as may be properly brought before the meeting or any adjournment thereof, conferring authority upon such true and lawful attorneys to vote in their discretion on such other matters as may properly come before the meeting and revoking any proxy heretofore given.

THE SHARES REPRESENTED BY THIS PROXY WILL BE VOTED AS DIRECTED OR, IF NO DIRECTION IS GIVEN, (Reg 14a-4(b)(1)) SHARES WILL BE VOTED FOR THE PROPOSAL IN ITEM 1, FOR THE PROPOSAL IN ITEM 2, FOR THE PROPOSAL IN ITEM 3, AND AUTHORITY WILL BE DEEMED GRANTED TO VOTE UPON SUCH OTHER MATTERS AS MAY PROPERLY COME BEFORE THE MEETING.

All votes must be received by 11:59 P.M., Eastern Time, ●, 2017.



**PROXY TABULATOR FOR
 TOKAI PHARMACEUTICALS, INC.
 c/o MEDIANT COMMUNICATIONS
 P.O. BOX 8016
 CARY, NC 27512-9903**

EVENT #

CLIENT #

