UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2017

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-36620

NOVUS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-1000967**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
19900 MacArthur Blvd., Suite 550 Irvine, California	**92612**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (949) 238-8090

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a small reporting company)	Small reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

As of November 6, 2017, there were 7,085,414 shares of the Registrant's common stock outstanding.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. Any statements in this Quarterly Report on Form 10-Q about the company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, the review of strategic alternatives and the outcome of such review and other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "could," "may," and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding:

- expectations regarding the timing for the commencement and completion of product development or clinical trials;
- the rate and degree of market acceptance and clinical utility of the company's products;
- the company's commercialization, marketing and manufacturing capabilities and strategy;
- the company's intellectual property position and strategy;
- the company's ability to identify additional products or product candidates with significant commercial potential;
- the company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to the company's competitors and industry; and
- the impact of government laws and regulations.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the ability to develop commercially viable product formulations; the sufficiency of the company's cash resources; the ability to obtain necessary regulatory and ethics approvals to commence additional clinical trials; whether data from early clinical trials will be indicative of the data that will be obtained from future clinical trials; whether the results of clinical trials will warrant submission for regulatory approval of any investigational product; whether any such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies and, if we are able to obtain such approval for an investigational product, whether it will be successfully distributed and marketed. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ significantly from the forward-looking statements contained herein, are described in greater detail in Item 1A. of Part II, *Risk Factors*. Any forward-looking statements contained in this Quarterly Report on Form 10-Q speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

NOVUS THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

NOVUS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	September 30, 2017	December 31, 2016 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,094	$ 1,103
Restricted cash	—	14
Prepaid expenses and other current assets	1,941	33
Total current assets	21,035	1,150
Property and equipment, net	47	31
Restricted cash	70	—
Goodwill	1,867	—
Other assets	—	15
Total assets	$ 23,019	$ 1,196
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 189	$ 338
Accrued severance	963	—
Accrued expenses and other liabilities	1,154	113
Convertible notes	—	3,447
Total current liabilities	2,306	3,898
Long-term liabilities	94	—
Total liabilities	2,400	3,898
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at September 30, 2017; preferred stock, $0.0026 par value, 6,565,540 shares authorized and 452,706 shares issued and outstanding at December 31, 2016	—	11
Common stock, $0.001 par value, 200,000,000 shares authorized and 6,943,058 shares issued and outstanding at September 30, 2017; common stock, $0.0026 par value, 9,207,060 shares authorized and 82,246 shares issued and outstanding at December 31, 2016	7	1
Additional paid-in capital	46,008	11,385
Receipts on account of Preferred A stock	—	291
Accumulated deficit	(25,396)	(14,390)
Total stockholders' equity (deficit)	20,619	(2,702)
Total liabilities and stockholders' equity (deficit)	$ 23,019	$ 1,196

See accompanying notes to unaudited condensed consolidated financial statements.

NOVUS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses				
Research and development	$ 517	$ 1,053	$ 1,529	$ 2,335
General and administrative	2,448	564	9,487	1,326
Total operating expenses	2,965	1,617	11,016	3,661
Loss from operations	(2,965)	(1,617)	(11,016)	(3,661)
Other income (expense), net	(5)	(418)	10	(479)
Net loss and comprehensive loss	$ (2,970)	$ (2,035)	$ (11,006)	$ (4,140)
Net loss per share, basic and diluted (Note 2)	$ (0.43)	$ (4.35)	$ (2.25)	$ (9.09)
Weighted-average common shares outstanding, basic and diluted	6,943,058	81,339	3,845,258	79,026

See accompanying notes to unaudited condensed consolidated financial statements.

NOVUS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Nine Months Ended September 30,	
	2017	**2016**
Operating activities		
Net loss	$ (11,006)	$ (4,140)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18	16
Stock-based compensation	386	142
Loss on disposal of fixed assets	31	—
Fair value of debt in excess of proceeds	—	517
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(761)	42
Accounts payable and accrued expenses	(998)	(218)
Net cash used in operating activities	(12,330)	(3,641)
Investing activities		
Cash received from merger transaction	23,250	—
Proceeds from sale of equipment	8	—
Purchase of property and equipment	—	(12)
Net cash provided by (used in) investing activities	23,258	(12)
Financing activities		
Proceeds from issuance of common stock, net	4,000	—
Proceeds from exercise of warrants	3,119	—
Proceeds from convertible loan	—	2,930
Net cash provided by financing activities	7,119	2,930
Net increase (decrease) in cash, cash equivalents and restricted cash	18,047	(723)
Cash, cash equivalents and restricted cash at beginning of period	1,117	3,095
Cash, cash equivalents and restricted cash at end of period	$ 19,164	$ 2,372
Supplemental disclosure of cash flow information		
Noncash activities:		
Conversion of promissory notes and interest to common stock	$ 3,447	$ —
Conversion of contingently issuable shares to common stock	$ 291	$ —
Fair value of assets acquired and liabilities assumed in the merger:		
Fair value of assets acquired, excluding cash and restricted cash	$ 3,072	
Fair value of liabilities assumed	(2,947)	
Fair value of net assets acquired in the merger	$ 125	

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1. Description of Business

Novus Therapeutics, Inc. is a development-stage, specialty pharmaceutical company focused on the development of products for disorders of the ear, nose, and throat ("ENT"). Unless otherwise indicated, references to the terms the "combined company", "Novus", the "Company", refer to Otic Pharma, Ltd. prior to the consummation of the Reverse Merger, and Novus Therapeutics, Inc., upon the consummation of the Reverse Merger described herein. The term "Tokai" refers to Tokai Pharmaceuticals, Inc., and its subsidiaries prior to the Reverse Merger.

Novus, a Delaware corporation, owns 100% of the issued and outstanding common stock or other ownership interest in Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel. Otic Pharma, Ltd. ("Otic") owns 100% of the issued and outstanding common stock or other ownership interest in its U.S. subsidiary, Otic Pharma, Inc.

All intercompany transactions between the consolidated entities are eliminated in consolidation.

Reverse Merger

On December 21, 2016, Tokai, a Delaware corporation, Otic, and the shareholders of Otic (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 agreed to sell to Tokai, and Tokai agreed to purchase from each Seller, all of the common and preferred shares of Otic ("Otic Shares") owned by such Seller in exchange for the issuance of a certain number of shares of common stock of Tokai, as determined pursuant to the terms of the Share Purchase Agreement (the "Reverse Merger"). The parties amended and restated the Share Purchase Agreement on March 2, 2017.

On May 9, 2017, Tokai, Otic, and the Sellers closed the transaction contemplated by the Share Purchase Agreement, and subsequently effected a reverse stock split at a ratio of one-for-nine (see *Reverse Stock-Split* below). On a post-split basis, Tokai issued to the Sellers an aggregate of 4,027,693 shares of Tokai's common stock in exchange for 836,857 Otic Shares. Following the completion of the Reverse Merger, the business being conducted by Tokai became primarily the business conducted by Otic. In connection with the Reverse Merger, the name of the surviving corporation was changed to "Novus Therapeutics, Inc."

Private Placement

On January 31, 2017, Novus entered into a stock purchase agreement (the "Stock Purchase Agreement") with certain purchasers named therein (the "Purchasers"), pursuant to which the Purchasers agreed to purchase approximately $4 million of the Company's common stock through the purchase of 400,400 shares of the Company's common stock at a price of $9.99 per share (the "Private Placement"). The Private Placement closed on May 10, 2017. After giving effect to the issuance of the shares in the Private Placement, the shareholders of Otic owned approximately 64% of the Company's common stock.

Reverse Stock-Split

On May 11, 2017, Novus effected a reverse stock-split of its issued and outstanding common stock and options for common stock at a ratio of one-for-nine. The Company filed an Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware effecting such reverse stock-split. The accompanying condensed consolidated financial statements and notes give retroactive effect to the reverse stock-split for all periods presented.

Liquidity and Financial Condition

The Company has adopted Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 205-40, *Presentation of Financial Statements – Going Concern*, which requires that management evaluate whether there are relevant conditions and events that, in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern and to meet its obligations as they become due within one year after the date that the financial statements are issued.

The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company recorded a net loss of $11.0 million for the nine months ended September 30, 2017. As of September 30, 2017, the Company had cash and cash equivalents of $19.1 million, working capital of $18.7 million and an accumulated deficit of $25.4 million. Management estimates that the Company has sufficient cash resources to meet anticipated cash needs through at least the next 12 months from the date of issuance of these financial statements. Due to continuing research and development activities, the Company expects to continue to incur net losses into the foreseeable future. In order to continue these activities, the Company may need to raise additional funds through future public or private debt and equity financings or strategic collaboration and licensing arrangements. If the Company issues equity or convertible debt securities to raise additional funding, its existing stockholders may experience dilution, it may incur significant financing costs, and the new equity or convertible debt securities may have rights, preferences and privileges senior to those of its existing stockholders. If the Company issues debt securities to raise additional funding, it would incur additional debt service obligations, it could become subject to additional restrictions limiting its ability to operate its business, and it may be required to further encumber its assets. Sufficient additional funding may not be available or be available on acceptable terms. If so, the Company may need to delay, reduce the scope of, or put on hold research and development activities while the Company seeks strategic alternatives.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and Article 10 of Regulation S-X requirements as set forth by the Securities and Exchange Commission ("SEC") for interim financial information and reflect all adjustments and disclosures, which are, in the opinion of management, of a normal and recurring nature, and considered necessary for a fair presentation of the financial information contained herein. The unaudited condensed consolidated financial statements do not include all information and notes necessary for a complete presentation of results of operations and comprehensive loss, financial position, and cash flows in conformity with GAAP.

The accompanying unaudited condensed consolidated financial statements and notes should be read in conjunction with the audited financial statements and accompanying notes of Otic for the year ended December 31, 2016 included in the definitive proxy statement on Schedule 14A relating to the Reverse Merger filed by the Company with the SEC on April 7, 2017. The results of operations and comprehensive loss for the three and nine months ended September 30, 2017 are not necessarily indicative of results expected for the full fiscal year or any other future period.

There have been no significant and material changes in our critical accounting policies and significant judgments and estimates during the three and nine months ended September 30, 2017, except as described below.

Use of Estimates

The preparation of the Company's financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to the valuation of certain financial instruments, stock-based compensation, and accruals for liabilities and other matters that affect the condensed consolidated financial statements and related disclosures. Actual results could differ materially from those estimates under different assumptions or conditions and the differences may be material to the consolidated financial statements.

Business Combinations

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development and liabilities assumed. Additionally, the Company must determine whether an acquired entity is considered a business or a set of net assets because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. The Company accounted for the merger with Tokai as a business combination under the acquisition method of accounting. Consideration paid to acquire Tokai was measured at fair value and included the exchange of Tokai's common stock and preferred stock. The allocation of the purchase price resulted in recognition of intangible assets related to goodwill. The operating activity for Tokai, the acquiree for accounting purposes, was immediately integrated with Otic post-merger, therefore it is not practical to segregate results of operations related specifically to Tokai since the date of acquisition.

As a result of the Reverse Merger, historical common stock, stock options and additional paid-in capital, including share and per share amounts, have been retroactively adjusted to reflect the equity structure of the Company.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired under the acquisition method of accounting. Goodwill is not amortized but is evaluated for impairment during the last fiscal quarter of the year or if indicators of impairment exist that would, more likely than not, reduce the fair value from its carrying amount.

Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, preferred stock, convertible notes and accrued interest, and stock options and warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share was the same for the periods presented due to the Company's net loss position.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In thousands, except share and per share data)			
Net loss available to stockholders of the company	$ (2,970)	$ (2,035)	$ (11,006)	$ (4,140)
Interest accumulated on preferred shares and on preferred shares contingently issuable for little or no cash	—	(458)	(328)	(917)
Net loss attributable to shareholders of preferred shares and to shareholders of preferred shares contingently issuable for little or no cash	—	2,139	2,666	4,339
Net loss used in the calculation of basic and diluted loss per share	$ (2,970)	$ (354)	$ (8,668)	$ (718)
Net loss per share, basic and diluted	$ (0.43)	$ (4.35)	$ (2.25)	$ (9.09)
Weighted-average number of common shares	6,943,058	81,339	3,845,258	79,026

The computation of diluted earnings per share excludes stock options, warrants, and restricted stock units that are anti-dilutive. For the three and nine months ended September 30, 2017, common share equivalents of 710,898 shares and 462,012 shares were anti-dilutive, respectively. For the three and nine months ended September 30, 2016, common share equivalents of 337,665 shares were anti-dilutive.

Stock-based Compensation

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the period the Company expects to receive services from the non-employee. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms.

For the nine months ended September 30, 2017, no excess tax benefits for tax deductions related to share-based awards were recognized in the accompanying consolidated statements of operations as no stock options were exercised.

Recently Issued Accounting Pronouncements

In January 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, which updates certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU No. 2016-01 will be effective for the Company beginning in its first quarter of 2018. The adoption of ASU No. 2016-01 is not expected to have a material impact on the Company's condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 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 the 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 condensed consolidated financial statements of the adoption of this guidance.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which modifies the measurement of expected credit losses of certain financial instruments. ASU No. 2016-13 will be effective for the Company beginning in its first quarter of 2020 and early adoption is permitted. The adoption of ASU No. 2016-13 is not expected to have a material impact on the Company's condensed consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory*, which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. ASU No. 2016-16 will be effective for the Company in its first quarter of 2018. The Company is currently evaluating the impact of adopting ASU No. 2016-16 on its condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Clarifying the Definition of a Business (Topic 805)*, which clarifies and provides a more robust framework to use in determining when a set of assets and activities is a business. The amendments in this update should be applied prospectively on or after the effective date. This update is effective for annual periods beginning after December 15, 2017, and interim periods within those periods. Early adoption is permitted for acquisition or deconsolidation transactions occurring before the issuance date or effective date and only when the transactions have not been reported in issued financial statements or made available for issuance financial statements. The Company is in the process of determining the effects the adoption will have on its consolidated financial statements as well as whether to early adopt the new guidance.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles – Goodwill and Other (Topic 350)*, which eliminates the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. The standard has tiered effective dates, starting in 2020 for calendar-year public business entities that meet the definition of an SEC filer. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. The Company is in the process of determining the effects the adoption will have on its consolidated financial statements as well as whether to early adopt the new guidance.

Recently Adopted Accounting Pronouncements

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. 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 periods beginning after December 15, 2016, including interim periods within that reporting period, with early adoption permitted. The Company early adopted ASU No. 2016-09 in the fourth quarter of 2016 and the adoption did not have a material impact on its condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statements of Cash Flows (Topic 230): Classification and Presentation of Restricted Cash in the Statements of Cash Flows*, which requires that restricted cash and restricted cash equivalents be included as components of total cash and cash equivalents in the statement of cash flows. The Company adopted the provisions of this guidance using the retrospective approach in the first quarter of 2017. The adoption did not have a material impact on its condensed consolidated financial statements but did impact the presentation of the cash flow statement.

The standard update is designed to minimize the diversity that exists in the classification and presentation of changes in restricted cash on the statement of cash flows and disclose the nature of the restrictions on cash and cash equivalents. The Company believes the changes will provide insight into the availability of amounts generally described as restricted cash and restricted cash equivalents on the balance sheet and will help users better understand the sources and uses of restricted cash and restricted cash equivalents during a reporting period.

A reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows, is as follows (in thousands):

	September 30, 2017	December 31, 2016
Cash and cash equivalents	$ 19,094	$ 1,103
Restricted cash, as part of current assets	—	14
Restricted cash, as part of long term assets	70	—
Total cash, cash equivalents, and restricted cash shown in the condensed consolidated statements of cash flows	$ 19,164	$ 1,117

Amounts included in restricted cash as part of current assets represented those required to be set aside as security for lease payments for Otic's Israel facility as of December 31, 2016. Restricted cash as part of long term assets on the condensed consolidated balance sheet as of September 30, 2017, represents amounts set aside to maintain a letter of credit for the benefit of the landlord of Tokai's Boston office.

Note 3. Reverse Merger

We completed the Reverse Merger with Tokai as discussed in Note 1. Based on the terms of the Reverse Merger, the Company concluded that the transaction is a business combination pursuant to ASC 805 *Business Combinations*, Otic was deemed the acquiring company for accounting purposes, and the transaction has been accounted for as a reverse acquisition under the acquisition method of accounting for business combinations in accordance with GAAP. 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 Reverse Merger closing date. The excess of the purchase price over the fair value of assets acquired and liabilities assumed was allocated to goodwill.

On May 9, 2017, Tokai issued 4,027,693 shares of its common stock to the shareholders of Otic and the holders of warrants and options of Otic upon the exercise of such options and warrants in exchange for 836,857 Otic Shares.

Purchase Consideration

The purchase price for Tokai on May 9, 2017, the closing date of the Reverse Merger, was as follows (in thousands):

Fair value of Tokai common stock outstanding (1)	$ 14,486
Premium paid (2)	8,889
Purchase price	$ 23,375

(1) Comprised of 2,515,739 shares of common stock outstanding at the date of the Reverse Merger based on the closing price of $5.76 per share on May 9, 2017, as adjusted for the one-for-nine reverse stock-split on May 11, 2017.

(2) Premium paid over fair value of common stock based on net tangible asset multiple of 1.08x book value of Tokai equity of $21.5 million as of May 9, 2017.

Allocation of Purchase Consideration

The allocation of the estimated purchase price to the acquired assets and liabilities assumed of Tokai, based on their estimated fair values as of May 9, 2017, the close of the transaction, is as follows (in thousands):

Cash, cash equivalents, and restricted cash	$ 23,250
Prepaids and other current assets	1,132
Property and equipment	73
Goodwill	1,867
Accounts payable, accrued expenses and other liabilities	(2,947)
Net assets acquired	$ 23,375

The Company engaged a third-party valuation firm to assist management in its analysis of the fair value of Tokai. All estimates, key assumptions, and forecasts were either provided by or reviewed by management. While the Company chose to utilize a third-party valuation firm, the fair value analysis and related valuations represent the conclusions of management and not the conclusions or statements of any third party. The excess of the total purchase price over the fair value of assets acquired and liabilities assumed was allocated to goodwill.

The Company believes that the historical values of Tokai's current assets and current liabilities approximate fair value based on the short-term nature of such items.

Goodwill is calculated as the difference between the fair value of the consideration expected to be transferred and the values assigned to the identifiable tangible and intangible assets acquired and liabilities assumed. Goodwill is not expected to be deductible for tax purposes.

The unaudited financial information in the following table summarizes the combined results of operations of the Company and Tokai, on a pro forma basis, as if the Reverse Merger had occurred at the beginning of the periods presented
(in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses				
Research and development	$ 517	$ 7,215	$ 1,988	$ 26,323
General and administrative	2,270	3,710	7,744	11,701
Total operating expenses	2,787	10,925	9,732	38,024
Loss from operations	(2,787)	(10,925)	(9,732)	(38,024)
Other income, net	(5)	137	50	179
Net loss and comprehensive loss	$ (2,792)	$ (10,788)	$ (9,682)	$ (37,845)
Net loss per share, basic and diluted	$ (0.40)	$ (1.60)	$ (1.39)	$ (5.60)
Weighted-average shares outstanding, basic and diluted	6,943,058	6,762,903	6,943,058	6,752,923

The above unaudited pro forma information was determined based on historical GAAP results of Otic and Tokai. The unaudited pro forma combined results are not necessarily indicative of what the Company's combined results of operations would have been if the acquisition was completed at the beginning of the periods presented. The unaudited pro forma combined net loss includes pro forma adjustments primarily relating to the following non-recurring items directly attributable to the business combination:

- Elimination of transaction costs of $178,000 and $7.2 million incurred during the three and nine months ended September 30, 2017, respectively. 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.
- Elimination of a fair value adjustment of $517,000 related to the convertible note issued on July 11, 2016.
- 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 Reverse Merger and Private Placement.

The combined aggregate transaction costs of the Company were $7.9 million, which were expensed as incurred.

Note 4. Fair Value

Financial assets and liabilities are recorded at fair value. At September 30, 2017, the Company had no financial instruments. At December 31, 2016, the Company's financial instruments included short-term convertible debt. The carrying amount of the short-term convertible debt approximates fair value due to the short-term maturities of these 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.

There have been no transfers of assets for liabilities between these fair value measurement classifications during the periods presented.

The Company had no financial assets or liabilities measured at fair value on a recurring basis at September 30, 2017.

The following table summarizes the Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2016 (in thousands):

	Level 1	Level 2	Level 3	Total
Liabilities				
Convertible notes	$ —	$ 3,447	$ —	$ 3,447
Total liabilities at fair value	$ —	$ 3,447	$ —	$ 3,447

Note 5. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following as of September 30, 2017 and December 31, 2016 (in thousands):

	September 30, 2017	December 31, 2016
Accrued clinical	$ 309	$ —
Accrued compensation and related expenses	445	51
Accrued professional services	276	—
Accrued vacation	102	50
Accrued other	22	12
Total accrued expenses and other liabilities	$ 1,154	$ 113

Note 6. Convertible Loan

On July 11, 2016, OrbiMed Israel Partners Limited Partnership and Peregrine Management II Ltd. provided Otic with a convertible bridge financing (the "Bridge Financing") in the aggregate amount of $2.9 million (the "Bridge Financing Amount"), pursuant to a Bridge Financing Agreement (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 Preferred C Shares of Otic at a price per share representing 85% of the Preferred C Shares' original issue price. Upon closing of the Reverse Merger, pursuant to the terms of the Bridge Financing Agreement, the Bridge Financing amount converted into 67,427 shares of common stock.

The Company concluded the value of the Bridge Financing 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. Accordingly, the Bridge Financing was classified as debt and was remeasured at its fair value of $3.4 million. As of September 30, 2017, the Company has no convertible debt.

Note 7. Commitments and Contingencies

Leases

The Company leases office space and equipment under various operating leases. These leases are generally subject to scheduled base rent and maintenance cost increases, which are recognized on a straight-line basis over the term of the leases. Total rental expense for all operating leases in the accompanying condensed consolidated statements of operations and comprehensive loss was $252,000 and $54,000 for the three months ended September 30, 2017 and 2016, respectively, and $455,000 and $164,000 for the nine months ended September 30, 2017 and 2016, respectively.

Restricted Cash and Letter of Credit

The Company is required to maintain a letter of credit totaling $70,000 for the benefit of the landlord of Tokai's Boston office. The landlord can draw against the letter of credit in the event of default by the Company. The Company held $70,000, which is in restricted cash as part of long term assets on the condensed consolidated balance sheet as of September 30, 2017. As of December 31, 2016, the Company maintained a $14,000 restricted cash balance that was used as security for lease payments for Otic's Israel facility and was invested in highly liquid deposits with original maturities of less than three months.

Grants and Licenses

From 2012 through 2015, the Company received grants in the amount of approximately $537,000 from the Office of Chief Scientist of the Israeli Ministry of Economy and Industry designated for investments in research and development. The grants are linked to the U.S. dollar and bear annual interest of LIBOR. The grants are to be repaid out of royalties from sales of the products developed by the Company from their investments in research and development. Because the Company has not yet earned revenues related to these investments and cannot estimate potential royalties, no liabilities related to these grants have been recorded as of each period presented.

In November 2015, the Company entered into an exclusive license agreement with Scientific Development and Research, Inc. and Otodyne, Inc. (collectively, the "Licensors") granting it an exclusive worldwide rights to develop and commercialize OP-02, a potential first-in-class treatment option for patients at risk for or with otitis media (middle ear inflammation with or without infection), which is often caused by Eustachian tube dysfunction. Under the terms of the agreement, the Company is obligated to use commercially reasonable efforts to seek approval for and commercialize at least one product for otitis media in the U.S. and key European markets (France, Germany, Italy, Spain, and the United Kingdom). The Company is responsible for prosecuting, maintaining, and enforcing all intellectual property and will be the sole owner of improvements. Under the agreement with the Licensors, the Company paid license fees totaling $700,000 and issued 9,780 common shares to the Licensors.

In December 2015, the Licensors completed transfer of all technology, including the active Investigational New Drug application ("IND") to the Company. The Company 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. The Company is also obligated to pay up to $36.0 million in sales based milestones, beginning with sales exceeding $1.0 billion in a calendar year. The Company 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 a low-single to mid-single percentage of net sales.

The Company has a master license agreement with the University of Maryland, Baltimore ("UMB"), which was originally entered into by Tokai. Pursuant to the license agreement, UMB granted an exclusive, worldwide license, with the right to sublicense, and, 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 $10,000 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 $50,000 for the filing of each additional investigational new drug application filed for a licensed product, aggregate milestone payments of up to $150,000 associated with the development of a licensed product for a particular non-prostate disease indication, and a $100,000 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, 2017 or 2016.

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 the 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 $50,000 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, 2017, 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 (through Tokai) 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, and 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 $75,000 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 $30,000 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 $700,000 in the aggregate. During the year ended December 31, 2015, the Company expensed $50,000 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, 2017, the Company has not yet developed a commercial product using the licensed technologies.

On October 5, 2017, the Company submitted notice of termination to all parties. The Company will no longer have any obligations to UMB after December 4, 2017, and to John Hopkins after January 3, 2018.

Legal Matters

The Company is involved in various lawsuits and claims arising in the ordinary course of business, including actions with respect to intellectual property, employment, and contractual matters. In connection with these matters, the Company assesses, on a regular basis, the probability and range of possible loss based on the developments in these matters. A liability is recorded in the financial statements if it is believed to be probable that a loss has been incurred and the amount of the loss can be reasonably estimated. Because litigation is inherently unpredictable and unfavorable results could occur, assessing contingencies is highly subjective and requires judgments about future events. The Company regularly reviews outstanding legal matters to determine the adequacy of the liabilities accrued and related disclosures. The amount of ultimate loss may differ from these estimates. Each matter presents its own unique circumstances, and prior litigation does not necessarily provide a reliable basis on which to predict the outcome, or range of outcomes, in any individual proceeding. Because of the uncertainties related to the occurrence, amount, and range of loss on any pending litigation or claim, the Company is currently unable to predict their ultimate outcome, and, with respect to any pending litigation or claim where no liability has been accrued, to make a meaningful estimate of the reasonably possible loss or range of loss that could result from an unfavorable outcome. In the event that opposing litigants in outstanding litigation proceedings or claims ultimately succeed at trial and any subsequent appeals on their claims, any potential loss or charges in excess of any established accruals, individually or in the aggregate, could have a material adverse effect on the Company's business, financial condition, results of operations, and/or cash flows in the period in which the unfavorable outcome occurs or becomes probable, and potentially in future periods.

Legal Proceedings

Doshi Action

On August 1, 2016, a purported stockholder of Tokai filed a putative class action lawsuit in the U.S. District Court for the Southern District of New York against Tokai, Jodie P. Morrison, and Lee H. Kalowski, entitled *Doshi v. Tokai Pharmaceuticals, Inc., et al.,* No. 1:16-cv-06106 ("Doshi Action"). The plaintiff sought to represent a class of purchasers of Tokai 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 Tokai's clinical trials for its drug candidate, galeterone. The lawsuit sought, 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 September 28, 2017, this action was consolidated with *Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al.,* No. 1:16-cv-11963 (see below). Given the uncertainty of litigation, the preliminary stage of the case, and the legal standards that must be met for, among other things, success on the merits, we are unable to predict the ultimate outcome of these actions, and therefore we cannot estimate the reasonably possible loss or range of loss that may result from this action.

Legal Proceedings Related to Tokai IPO

On September 22, 2014, Tokai completed the initial public offering of its common stock (the IPO"). Subsequent to the IPO, several lawsuits were filed against Tokai, Jodie Pope Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of the IPO. The lawsuits allege that, in violation of the Securities Act of 1933 ("Securities Act"), Tokai's registration statement for the IPO made false and misleading statements and omissions about Tokai's clinical trials for galeterone. Each lawsuit sought, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees. Further details on each lawsuit are set forth below. Given the uncertainty of litigation, the preliminary stage of these cases, and the legal standards that must be met for, among other

things, success on the merits, we are unable to predict the ultimate outcome of these actions, and therefore we cannot estimate the reasonably possible loss or range of loss that may result from these actions.

- Jackie888 Action. On August 19, 2016, a purported stockholder of Tokai filed a putative class action lawsuit in the Superior Court of the State of California, County of San Francisco, entitled *Jackie888, Inc. v. Tokai Pharmaceuticals, Inc., et al.,* No. CGC-16-553796. The plaintiff sought to represent a class of purchasers of Tokai common stock in or traceable to Tokai's IPO. 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 February 27, 2017, the Superior Court entered an order granting defendants' motion to stay the lawsuit.
- Garbowski Action. On September 29, 2016, two purported stockholders of Tokai filed a putative class action lawsuit in the U.S. District Court for the District of Massachusetts, entitled *Garbowski, et al. v. Tokai Pharmaceuticals, Inc., et al.,* No. 1:16-cv-11963 ("Garbowski Action"). In addition to the Securities Act claims, this lawsuit also alleges that the defendants made false and misleading statements and omissions about Tokai's clinical trials for galeterone, in violation of the Exchange Act and Rule 10b-5 promulgated thereunder. The plaintiffs sought to represent a class of purchasers of Tokai common stock in or traceable to Tokai's IPO as well as a class of purchasers of Tokai common stock between September 17, 2014, and July 25, 2016. On September 28, 2017, this action was consolidated with the Doshi Action.
- Wu Action. On December 5, 2016, a putative securities class action was filed in the Business Litigation Session of the Superior Court Department of the Suffolk County Trial Court, Massachusetts ("Massachusetts State Court"), entitled *Wu v. Tokai Pharmaceuticals, Inc., et al.,* 16-3725 BLS ("Wu Action"). The plaintiff seeks to represent a class of purchasers of Tokai common stock in or traceable to Tokai's IPO. On December 19, 2016, defendants removed the Wu Action to the U.S. District Court for the District of Massachusetts, where it was captioned *Wu v. Tokai Pharmaceuticals, Inc., et al.,* 16-cv-12550, and assigned to the same judge presiding over the Doshi and Garbowski Actions. On December 22, 2016, defendants filed a motion to consolidate the Wu Action with the Doshi and Garbowski Actions. On January 6, 2017, plaintiff filed a motion to remand the Wu Action to Massachusetts State Court. On September 28, 2017, the court stayed the case pending a decision by the *United States Supreme Court in Cyan, Inc. v. Beaver County Employees Retirement Fund*, S. Ct. Case No. 15-1439.
- Angelos Action. On July 25, 2017, a purported stockholder of Tokai filed a lawsuit in the U.S. District Court for the District of Massachusetts, entitled *Peter B. Angelos v. Tokai Pharmaceuticals, Inc., et al.,* No. 1:17-cv-11365-MLW. The case has been assigned to the same judge presiding over the Doshi, Garbowski, and Wu Actions.

Legal Proceedings Related to Reverse Merger

In connection with the Reverse Merger, two putative securities class actions have been filed in the U.S. District Court for the District of Massachusetts against Tokai, Jodie P. Morrison, Seth L. Harrison, Stephen Buckley, Jr., Cheryl L. Cohen, David A. Kessler, and Joseph A. Yanchik, III. The two complaints are captioned as follows: *Bushansky v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-10621-DPW (filed April 11, 2017), and *Wilson v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-10645-DPW (filed April 14, 2017). Each lawsuit alleges that Tokai's definitive proxy statement on Schedule 14A filed with the SEC on April 7, 2017 (the "Definitive Proxy Statement") made false and misleading statements and omissions in connection with the Reverse Merger, in violation of the Exchange Act and Rule 14a-9, promulgated thereunder. Each plaintiff sought to represent a class of all persons and entities that owned Tokai common stock. Each lawsuit sought, among other things, preliminary and permanent injunctions of the Reverse Merger unless Tokai disclosed certain information requested by plaintiff, rescission and unspecified damages if the Reverse Merger is consummated, and attorneys' fees. These two actions are collectively referred to as the "Stockholder Litigation." On June 6, 2017, each of the plaintiffs in the two actions constituting the Stockholder Litigation, voluntarily dismissed the actions with prejudice as to such plaintiff only and without prejudice as to the putative class in the action.

In May 2017, the Company entered into a settlement agreement with the two complainants resolving the Stockholder Litigation. Under the terms of the settlement, the Company filed a Form 8-K on April 28, 2017, making certain disclosures that supplement and revise those contained in the Definitive Proxy Statement to avoid the risk of the Stockholder Litigation delaying or adversely affecting the closing of the Share Purchase Agreement and to minimize the expense of defending the Stockholder Litigation, and without admitting any liability or wrongdoing. The Company also remitted payment in the amount of $150,000 to resolve the plaintiffs' claim for attorneys' fees and expenses in full satisfaction of any of their claims for fees or costs.

The Company has always maintained and continues to believe that it did not engage in any wrongdoing or otherwise commit any violation of federal or state securities laws or other laws.

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 because 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, 2017.

Note 8. Income Taxes

The Company is subject to income taxes under the Israeli and U.S. tax laws. The Company was subject to an Israeli corporate tax rate of 25% in the year 2016 and will be subject to an Israeli corporate tax rate of 24% in the year 2017 and 23% in the year 2018 and thereafter. The Company was subject to a blended U.S. tax rate (Federal as well as state corporate tax) of 35% in 2016.

Note 9. Stockholders' Equity

Warrants

In March 2017, OrbiMed Israel Partners Limited Partnership, a related party, exercised a warrant to purchase 22,679 shares of Preferred B shares of the Company at $17.64 per share for an aggregate amount of approximately $400,000.

In May 2017, OrbiMed Israel Partners Limited Partnership, a related party, exercised warrants to purchase 149,686 shares of Preferred B shares and 10,737 Ordinary Shares of the Company at a weighted-average price of $16.46 per share for an aggregate amount of approximately $2.6 million.

In May 2017, Peregrine Management II Ltd., a related party, exercised warrants to purchase 4,460 shares of Preferred B shares and 2,148 Ordinary Shares of the Company at a weighted-average price of $11.91 per share for an aggregate amount of approximately $79,000.

In May 2017, Pontifax, in a cashless exercise of its warrants, purchased 18,940 Ordinary Shares of the Company.

Piper Jaffray Equity Distribution Agreement

On August 21, 2017, the Company entered into an equity distribution agreement (the "Equity Distribution Agreement") with Piper Jaffray & Co. ("Piper Jaffray"), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Piper Jaffray, up to $8.5 million in shares of its common stock. The Company has no obligation to sell any of the shares, and may at any time suspend offers under the Equity Distribution Agreement.

Note 10. Subsequent Events

On August 21, 2017, the Company entered into an Equity Distribution Agreement with Piper Jaffray, pursuant to which the Company may offer and sell shares of its common stock through Piper Jaffray. From October 2, 2017 through November 6, 2017, the Company had sold 142,356 shares of its common stock through Piper Jaffray under the Equity Distribution Agreement for gross proceeds of $653,000. Refer to Note 9 for additional information on the Equity Distribution Agreement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with our audited financial statements and accompanying notes for the year ended December 31, 2016 included in Item 9.01 of our Current Report on Form 8-K/A filed on July 25, 2017. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Please see Part II, Item 1A. *Risk Factors* for a discussion of certain risk factors applicable to our business, financial condition, and results of operations. Operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period. The term "Otic Pharma" refers to Novus Therapeutics, Inc., prior to the consummation of the Reverse Merger. Unless otherwise indicated, references to the terms the "combined company", "Novus", the "Company", "we", "our" and "us" refer to Otic Pharma, prior to the consummation of the Reverse Merger and Novus Therapeutics, Inc., upon the consummation of the Reverse Merger described herein. The term "Tokai" refers to Tokai Pharmaceuticals, Inc. prior to the Reverse Merger.

ABOUT NOVUS THERAPEUTICS

Novus Therapeutics, Inc. ("Novus") is a development-stage, specialty pharmaceutical company focused on the development of products for disorders of the ear, nose, and throat (ENT).

Novus, a Delaware corporation, owns 100% of the issued and outstanding common stock or other ownership interest in Otic Pharma, Ltd.("Otic"), a private limited company organized under the laws of the State of Israel. Otic owns 100% of the issued and outstanding common stock or other ownership interest in its U.S. subsidiary, Otic Pharma, Inc.

Novus has no products approved for commercial sale. Novus has not generated any revenue and has incurred significant operating losses in each year since its inception in 2008. Substantially all of Novus' operating losses resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations. Novus 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 acute otitis externa ("AOE" or "swimmers ear") and otitis media ("OM" or middle ear inflammation with or without infection). Novus 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 protect its proprietary technology and to mitigate the dependence on key individuals. Furthermore, due to the uncertainty of pharmaceutical product development, Novus may never achieve future revenue through product sales, licensing or partnership agreements.

OP-02 Surfactant Program

OP-02 is being developed as a potential first-in-class treatment option for patients at risk for or with OM, which is often caused by Eustachian tube dysfunction ("ETD"). Globally, OM affects more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice and in the United States 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. The Company has not manufactured a current Good Manufacturing Procedures ("cGMP") batch of OP-02 suitable for clinical trials. Subject to successful completion of formulation development and manufacture of a cGMP batch, the Company expects to initiate a phase 1 clinical program in 2018 to explore the safety and tolerability of OP-02 in healthy subjects. The phase 1 program will evaluate single and repeated intranasal doses of OP-02. Upon completion of the phase 1 program, Novus intends to initiate phase 2 and 3 studies of OP-02, with an initial focus on a development program that will lead to registration of OP-02 in North America and key European markets as a treatment to prevent acute OM, recurrent OM, and/or chronic OM in children. Additional development activities to support registration in other countries and/or for other OM disorders, or in other patient populations, may occur in the future.

OP-01 Foam Platform

OP-01 is being developed with the intent to be used as a delivery vehicle for drugs to be administered into the ears, as well as the nasal and sinus cavities. Specifically, OP-01 is being developed as an improved treatment option for AOE, a common medical condition of the outer ear canal that affects tens of millions of adults and children each year. Novus has completed four clinical trials of OP-01 in 353 adult and pediatric subjects, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP-01 that performed similarly to standard of care.

In 2016, Novus stopped development of the first-generation, antibiotic-only OP-01 product and began development of a second-generation formulation of OP-01. The goal for this second-generation formulation is to produce a clinically differentiated product that rapidly relieves ear pain (an unmet need in AOE) and eradicates infection with less than seven days of treatment. If approved, we believe OP-01 will meaningfully improve the standard of care and may become a best-in-class treatment option for AOE. Subsequent to the completion of the Reverse Merger, the Company paused the OP-01 development program and began focusing substantially all of its resources on the advancement of its surfactant program (OP-02) for middle ear disease.

RECENT DEVELOPMENTS

Reverse Merger

On December 21, 2016, Novus, formerly known as Tokai Pharmaceuticals, Inc. ("Tokai"), a Delaware corporation, and the shareholders of Otic (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 agreed to sell to Tokai, and Tokai agreed to purchase from each Seller, all of the common and preferred shares of Otic ("Otic Shares") owned by such Seller in exchange for the issuance of a certain number of shares of common stock of Tokai, as determined pursuant to the terms of the Share Purchase Agreement (the "Reverse Merger"). The parties amended and restated the Share Purchase Agreement on March 2, 2017.

On May 9, 2017, Tokai, Otic, and the Sellers closed the transaction contemplated by the Share Purchase Agreement and subsequently effected a reverse stock-split at a ratio of one-for-nine (see *Reverse Stock-Split* below). On a post-split basis, Tokai issued to the Sellers an aggregate of 4,027,693 shares of Tokai's common stock in exchange for 836,857 Otic Shares. Following the completion of the Reverse Merger, the business being conducted by Tokai became primarily the business conducted by Otic. Subsequent to the Reverse Merger, the name of the surviving corporation was changed to "Novus Therapeutics, Inc."

Private Placement

On January 31, 2017, Novus entered into the Share Purchase Agreement with the Purchasers, pursuant to which the Purchasers agreed to purchase approximately $4 million of the Company's common stock through the purchase of 400,400 shares of the Company's common stock at a price of $9.99 per share. The Private Placement closed on May 10, 2017. After giving effect to the issuance of the shares in the Private Placement, the shareholders of Otic owned approximately 64% of the Company's common stock.

Reverse Stock-Split

On May 11, 2017, Novus effected a reverse stock-split of its issued and outstanding common stock and options for common stock at a ratio of one-for-nine. The Company filed an Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware effecting the reverse stock-split. The accompanying condensed consolidated financial statements and notes give retroactive effect to the reverse stock-split for all periods presented.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements require us to make estimates and judgments that affect the reported amount of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities as of the date of the financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our 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. There have been no significant and material changes in our critical accounting policies and significant judgments and estimates during the three and nine months ended September 30, 2017, as compared to those disclosed in Exhibit 99.1 of our Current Report filed on Form 8-K/A filed on July 25, 2017, except as described below.

Business Combinations

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development and liabilities assumed. Additionally, we must determine whether an acquired entity is considered a business or a set of net assets because the excess

of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. We accounted for the Reverse Merger with Tokai as a business combination under the acquisition method of accounting. Consideration paid to acquire Tokai was measured at fair value and included the exchange of Tokai's common stock. The allocation of the purchase price resulted in recognition of goodwill.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired under the acquisition method of accounting. Goodwill is not amortized but is evaluated for impairment during the last fiscal quarter of the year or if indicators of impairment exist that would, more likely than not, reduce the fair value from its carrying amount.

Significant management judgment is required in the forecasts of future operating results that are used in our impairment evaluation. The estimates we have used are consistent with the plans and estimates that we use to manage our business. It is possible, however, that the plans may change and estimates used may prove to be inaccurate. If our actual results, or the plans and estimates used in the future impairment analyses, are lower than the original estimates used to assess the recoverability of these assets, we could incur future impairment charges.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended September 30, 2017 and 2016

The following table provides comparative unaudited results of operations for the three months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,			
	2017	2016	$ Variance	% Variance
Operating expenses:				
Research and Development	517	1,053	(536)	(51)%
General and Administrative	2,448	564	1,884	334%
Total operating expenses	2,965	1,617	1,348	83%
Loss from operations	(2,965)	(1,617)	(1,348)	83%
Other income (expense), net	(5)	(418)	413	(99)%
Net loss	$ (2,970)	$ (2,035)	(935)	46%

Research and Development Expenses

During the three months ended September 30, 2017, research and development expenses of $517,000 were primarily comprised of formulation development costs for OP-02 and clinical development costs for Tokai's legacy programs. During the three months ended September 30, 2016, research and development expenses of $1.1 million were comprised of expenses associated with the development of a second-generation formulation for OP-01 and development costs for OP-02. The decrease from period to period is primarily attributed to decreased spending on OP-01, offset by wind down costs incurred for legacy Tokai programs. We expect research and development expenses to increase in subsequent periods as we advance our OP-02 programs.

General and Administrative Expenses

General and administrative expenses increased in the 2017 period primarily due to the recognition of merger-related expenses, an increase in administrative costs associated with operating a public company and the ongoing legal costs related to Tokai's shareholder lawsuits.

Other Income (Expense), Net

The change in other income (expense), net was primarily related to the fair value adjustment for convertible notes incurred in the three months ended September 30, 2016. No such adjustment was necessary during the three months ended September 30, 2017 as the convertible notes were converted to common stock contemporaneously with the Reverse Merger.

Comparison of the Nine Months Ended September 30, 2017 and 2016

The following table provides comparative unaudited results of operations for the nine months ended September 30, 2017 and 2016 (in thousands):

	Nine Months Ended September 30,			
	2017	2016	$ Variance	% Variance
Operating expenses:				
Research and Development	1,529	2,335	(806)	(35)%
General and Administrative	9,487	1,326	8,161	615%
Total operating expenses	11,016	3,661	7,355	201%
Loss from operations	(11,016)	(3,661)	(7,355)	201%
Other income (expense), net	10	(479)	489	(102)%
Net loss	$ (11,006)	$ (4,140)	(6,866)	166%

Research and Development Expenses

During the nine months ended September 30, 2017, research and development expenses of $1.5 million were primarily comprised of OP-02 formulation development costs and clinical development costs for Tokai's legacy programs. During the nine months ended September 30, 2016, research and development expenses of $2.3 million were comprised of expenses associated with the development of a second-generation formulation for OP-01 and development costs for OP-02. The decrease from period to period is primarily attributed to decreased spending on OP-01, offset by wind down costs incurred for legacy Tokai programs. We expect research and development expenses to increase in subsequent periods as we advance our OP-02 programs.

General and Administrative Expenses

General and administrative expenses increased in the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, primarily due to the recognition of $7.2 million of merger and public company related expenses, including severance costs for Tokai employees, as well as the increase in administrative costs associated with operating as a public company and the ongoing legal costs related to Tokai's shareholder lawsuits.

Other Income (Expense), Net

The change in other income (expense), net was primarily related to the fair value adjustment for convertible notes incurred in the nine months ended September 30, 2016. No such adjustment was necessary during the nine months ended September 30, 2017 as the convertible notes were converted to common stock contemporaneously with the Reverse Merger.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2017, we had cash and cash equivalents of $19.1 million. See Part 1, Item 3, *Quantitative and Qualitative Disclosures About Market Risk*, for a discussion of potential risks associated with our cash and cash equivalents. To date, our operations have been financed primarily by net proceeds from the sale of preferred and common stock, the issuance of convertible promissory notes, and cash received in the Reverse Merger with Tokai. We believe our cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months from the date of issuance of these financial statements.

On May 9, 2017, we completed our Reverse Merger with Tokai, which provided $23.3 million in cash and cash equivalents. Immediately following the Reverse Merger, we raised $4.0 million in aggregate gross proceeds from a private placement of our common stock.

Our primary uses of capital are, and we expect will continue to be, funding research efforts and the development of our product candidates, compensation and related expenses, hiring additional staff (including clinical, scientific, operational, financial, and management personnel) and costs associated with operating as a public company. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates.

We plan to continue to fund losses from operations and capital funding needs through cash on hand and future equity or debt financings, as well as potential additional collaborations or strategic partnerships with other companies. During the three

months ended September 30, 2017, we entered into an equity distribution agreement pursuant to which we may sell shares of common stock from time to time in "at-the-market" offerings. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We can provide no assurance that financing will be available in the amounts we need or on terms acceptable to us, if at all. If we are not able to secure adequate additional funding we may be forced to delay, make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm our business.

Cash Flows

The following table provides a summary of our net cash flow activity (in thousands):

	Nine Months Ended September 30,	
	2017	2016
Net cash used in operating activities	$ (12,330)	$ (3,641)
Net cash provided by (used in) investing activities	23,258	(12)
Net cash provided by financing activities	7,119	2,930
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 18,047	$ (723)

Comparison of the Nine Months Ended September 30, 2017 and 2016

Net cash used in operating activities for the nine months ended September 30, 2017 consisted primarily of our net loss of $11.0 million, partially offset by non-cash items consisting primarily of depreciation, loss on disposal of fixed assets, and stock-based compensation totaling $435,000. Additionally, cash used in operating expenses for the nine months ended September 30, 2017 reflected a net decrease in cash from changes in operating assets and liabilities of $1.8 million, primarily due to an increase in our prepaid expenses and accrued liabilities.

Net cash used in operating activities for the nine months ended September 30, 2016 consisted primarily of our net loss of $4.1 million, partially offset by non-cash items consisting of depreciation, stock-based compensation, and fair value adjustment for convertible debt totaling $675,000. Additionally, cash used in operating expenses for the nine months ended September 30, 2017 reflected a net decrease in cash from changes in net operating assets and liabilities of $176,000, primarily due to an increase in our accrued expenses, partially offset by decreases in prepaid expenses and accounts payable.

Net cash provided by investing activities for the nine months ended September 30, 2017 consisted primarily of cash received from the Reverse Merger of $23.3 million.

Net cash used in investing activities for the nine months ended September 30, 2016 consisted of the purchase of property and equipment in the amount of $12,000.

Net cash provided by financing activities for the nine months ended September 30, 2017 was comprised of $4.0 million in proceeds from the Stock Purchase Agreement for the purchase of 400,400 shares of Novus common stock and proceeds from the exercise of warrants in the amount of $3.1 million. Cash provided by significant financing activities in the nine months ended September 30, 2016 consisted of $2.9 million in proceeds from a convertible bridge financing transaction.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

Contractual Arrangements

No material changes to contractual obligations and commitments occurred during the nine months ended September 30, 2017.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents as of September 30, 2017 consisted of readily available cash in bank accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on Novus's financial condition or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents are not subject to excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Item 4. Controls and Procedures.

Definition and Limitations of Disclosure Controls

Our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, such as this report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to our management, including the Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management evaluates these controls and procedures on an ongoing basis.

There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. These limitations include the possibility of human error, the circumvention or overriding of the controls and procedures and reasonable resource constraints. In addition, because we have designed our system of controls based on certain assumptions, which we believe are reasonable, about the likelihood of future events, our system of controls may not achieve its desired purpose under all possible future conditions. Accordingly, our disclosure controls and procedures provide reasonable assurance, but not absolute assurance, of achieving their objectives.

Evaluation of Disclosure Controls and Procedures

Our Principal Executive Officer and our Principal Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures, believe that as of the end of the period covered by this report, our disclosure controls and procedures were effective in providing the requisite reasonable assurance that material information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding the required disclosure.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting identified in connection with our evaluation that occurred during our most recent fiscal quarter that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

Information pertaining to legal proceedings is provided in Note 7, Commitments and Contingencies, to the condensed consolidated financial statements and is incorporated by reference herein.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in our annual report on Form 10-K and subsequent reports filed with the Securities and Exchange Commission. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline.

Unless otherwise indicated, references to the terms the "combined company", "Novus", the "Company", "we", "our", and "us" refer to Otic Pharma, Ltd., and subsidiary ("Otic") prior to the consummation of the Reverse Merger, and Novus Therapeutics, Inc., upon the consummation of the Reverse Merger described herein. The term "Tokai" refers to the Tokai Pharmaceuticals, Inc., and its subsidiaries ("Tokai") prior to the Reverse Merger.

Risks Related to Our Operations

We have incurred significant operating losses since our inception and expect that we will continue to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, Otic, the accounting acquirer in the Reverse Merger, has incurred significant operating losses. Otic's net loss was $5.7 million for the year ended December 31, 2016 and $4.2 million for the year ended December 31, 2015. As of December 31, 2016, Otic had an accumulated deficit of $14.4 million. The Company's net loss for the nine months ended September 30, 2017 is $11.0 million and the Company has an accumulated deficit of $25.4 million.

We are focused primarily on developing OP-02 as a potential first-in-class treatment option for patients at risk for or with otitis media ("OM") (middle ear inflammation with or without infection). We have not manufactured a cGMP batch of OP-02 suitable for clinical trials. Subject to successful completion of formulation development and manufacture of a cGMP batch, we expect to initiate a phase 1 clinical program in 2018 to explore the safety and tolerability of OP-02 in healthy subjects. The phase 1 program will evaluate single and repeated intranasal doses of OP-02. Upon completion of the phase 1 program, Novus intends to initiate phase 2 studies of OP-02, with an initial focus on prevention of acute, recurrent, and chronic OM in children. We expect that it will be several years, if ever, before we have a product candidate ready for commercialization. If we are unable to successfully complete the formulation of OP-02 and begin to generate clinical data for this program, we may have greater difficulty raising additional capital on favorable terms, or at all.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses that we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- continue formulation development of our product candidates;
- continue nonclinical and clinical development of our product candidates;
- seek to identify and acquire additional product candidates;
- acquire or in-license other products and technologies;
- enter into collaboration arrangements with regards to product discovery or development;
- develop manufacturing processes;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;

- hire additional personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- operate as a public company.

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

We are early in our development efforts and have only two drug candidates, OP-01 and OP-02. If we are unable to successfully develop and commercialize OP-01 or OP-02, or if we experience significant delays in doing so, our business will be materially harmed.

We currently do not have any products that have gained regulatory approval. We have invested substantially all of our efforts and financial resources in product development, including funding our formulation development, nonclinical, and clinical studies. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of OP-01, OP-02 or additional product candidates. As a result, our business is substantially dependent on our ability to successfully complete the development of and obtain regulatory approval for OP-01, OP-02, or additional product candidates.

We have 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 our business plan, we will need to successfully:

- execute OP-01 and OP-02 formulation, clinical, and nonclinical development activities;
- 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 our intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on our 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 we elect to enter into; and
- manage our spending as costs and expenses increase due to product manufacturing, nonclinical development, clinical trials, regulatory approvals, post-marketing commitments, and commercialization.

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

Our short operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are an early development stage pharmaceutical company. Our ongoing 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 nonclinical studies, and, up until the consummation of the Reverse Merger, early stage clinical studies of our most advanced product candidate, OP-01. Subsequent to the completion of the Reverse Merger, we paused the OP-01 development program and began focusing substantially all of our resources on the advancement of our surfactant program (OP-02) for middle ear disease. Operations related to OP-02 include arranging for third party vendors to formulate and manufacture material using current Good Manufacturing Procedures ("cGMP") and preparing for phase 1 clinical studies. We have not yet demonstrated our 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 our 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 our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history.

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

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. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the formulation and commercialization of our product candidates.

Reformulation work for OP-01 to explore adding a second active ingredient (anesthetic) to address immediate relief of ear pain associated with Acute Otitis Externa (infection/inflammation of the outer ear canal) commenced in 2016, but was subsequently put on hold until further funding is obtained. At such time as when we recommence development of OP-01, additional clinical studies with the new OP-01 combination formulation (antibiotic + anesthetic) will need to be conducted. There is a risk that additional nonclinical and/or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States and/or that subsequent studies will not match results seen in prior studies. We have not manufactured a cGMP batch of OP-02 suitable for clinical trials. Formulation development for OP-02 is ongoing. Subject to successful completion of formulation development and manufacture of a cGMP batch, we expect to initiate a phase 1 clinical program in 2018 to explore the safety and tolerability of OP-02 in healthy subjects. Given the early stage of development for both products, the risk of failure for both of our product candidates is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete formulation development for our products, conduct nonclinical trials, and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Formulation development, nonclinical and clinical testing are all expensive activities, difficult to design and implement, and can take years to complete. The outcome of nonclinical and clinical trials are inherently uncertain. Failure can occur at any time during the development program, including during the clinical trial process. Further, the results of nonclinical studies and early clinical trials of our product candidates, as well as earlier generation formulations may not be predictive of the results of later-stage clinical trials. Interim results of a clinical trial do not necessarily predict final results. For instance, the results of our 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, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans, or will receive regulatory approval.

We may experience delays in our clinical trials, and we do 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"), the Medicines & Healthcare Products Regulatory Agency (the "MHRA"), the UK regulatory authority, or the FDA will not put any of our product candidates on clinical hold in the future. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our 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 we want to execute;
- 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;
- delays in completing formulation work for OP-01 and OP-02 as a prerequisite to commencing clinical work on this program;
- 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 we 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 our contract research organizations ("CROs") and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience delays or difficulties in the enrollment of patients that our product candidates are designed to target;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have difficulty partnering with experienced CROs and study sites that can identify patients that our product candidates are designed to target and run our clinical trials effectively;
- regulators or institutional review boards ("IRBs") may require that we or our 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 our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our 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, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;

- be subject to additional post-marketing restrictions and/or testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to demonstrate safety and efficacy. We have yet to initiate the first clinical studies of OP-02 and plan to reformulate and initiate the clinical studies of OP-01 in the future, and we do 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 the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us 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 our clinical trials, or results that are inconsistent with earlier results;
- feedback from regulatory authorities, IRBs, ethics committees ("ECs"), or data safety monitoring boards, or results from earlier stage or concurrent nonclinical and clinical studies, that might require modifications to the protocol;
- decisions by regulatory authorities, IRBs, ECs, or the Company, 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.

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

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

If our product candidates are associated with undesirable effects in nonclinical or clinical trials or have characteristics that are unexpected, we 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. 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. Although the one reported serious adverse event in the 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 OP-01 clinical studies. To date, OP-02

has not been evaluated in any human clinical studies. Any occurrences of clinically significant adverse events may harm our business, financial condition and prospects significantly.

Risks Related to Our Financial Position and Need for Additional Capital

We will need substantial additional funding. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in parallel with our ongoing activities, particularly as we continue our nonclinical and clinical development, identify new clinical candidates and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our nonclinical and clinical development programs or any future commercialization efforts.

Based upon current operating plans, we expect our current working capital will be sufficient to fund our operations for at least the next 12 months. We 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. Our funding needs may fluctuate significantly based on a number of factors, such as:

- the scope, progress, results and costs of formulation development and manufacture of drug product to support nonclinical and clinical development of our product candidates;
- the extent to which we enter into additional collaboration arrangements regarding product discovery or development, or acquire or in-license products or technologies;
- our ability to establish additional collaborations with favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

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

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings and debt financings. We do not have any committed external source of funds. We have entered into an equity distribution agreement pursuant to which we may sell shares of common stock from time to time in "at-the-market" offerings. To the extent that we raise additional capital through this at-the-market offering facility or otherwise 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 our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts.

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

If existing stockholders of the Company sell, or indicate an intention to sell, substantial amounts of the Company's common stock in the public market after the Reverse Merger lock-up period and other legal restrictions on resale lapse, the trading price of the common stock of the combined company could decline. At September 30, 2017, the Company had approximately 6.9 million shares outstanding.

The Share Purchase Agreement by and among Tokai, Otic, and shareholders of Otic contains a lock-up covenant from the Otic shareholders, which provides that for 180 days following the closing of the Reverse Merger (November 5, 2017), no Otic shareholder shall offer, sell, or otherwise dispose of, directly or indirectly, any securities of the Company, or otherwise enter into a transaction that would have similar effect. Concurrent with the Reverse Merger, the company completed the Private Placement. A registration statement covering the resale of the shares of Company common stock issuable in connection with the Private Placement is in effect, allowing up to 400,400 shares of common stock to be sold in the public market. Further, shares held by directors, executive officers of the Company and other affiliates will be eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act, after November 5, 2017.

Because the Reverse Merger resulted in an ownership change under Section 382 of the Internal Revenue 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 post-merger 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 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The Reverse Merger resulted 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 Reverse Merger. 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 post-merger Company's net operating loss carryforwards. Consequently, even if the Company achieves profitability, it may not be able to utilize a material portion of Tokai's, Otic's, or the post-merger Company's net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

The failure to integrate successfully the businesses of Otic and Tokai in the expected timeframe could adversely affect the future results of the Company.

Our success will depend, in large part, on our ability 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 our failure to achieve some or all of the anticipated benefits of the Reverse Merger.

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 Reverse Merger and the operations of the combined company;
- potential unknown and unforeseen expenses or regulatory conditions associated with the Reverse Merger; and
- performance shortfalls as a result of the diversion of management's attention caused by integrating the companies' operations.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may be for a narrow indication, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired.

Our product candidates must be approved by the FDA pursuant to a new drug application in the United States and by other regulatory authorities outside the United States prior to commercialization. The process of obtaining marketing approvals, both in the United States and outside the United States, 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 us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any country. We have no experience in filing and supporting the applications necessary to gain marketing approvals for ear, nose, or throat (ENT) products and may engage third-party consultants to assist in this process. Securing marketing approval requires the submission of extensive nonclinical and clinical data, and other 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 formulation and manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our 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 our 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 our data are insufficient for approval and require additional nonclinical, clinical or other data. In addition, varying interpretations of the data obtained from nonclinical and clinical studies 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 we ultimately obtain 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 our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed outside the United States.

In order to market and sell our products in the European Union and other international jurisdictions outside of the United States, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may require additional nonclinical, clinical or health outcome data. In addition, the time required to obtain approval may differ substantially amongst international jurisdictions. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition to regulatory approval, 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. We 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. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Any product candidate for which we obtain 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 we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Our 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 that are specific to those defined by regulatory authorities in the countries where the product is

approved. In the United States and other countries that follow the International Conference on Harmonization (ICH), 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 we promote our products beyond their approved indications, we 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 our 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;
- 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 we submit;
- 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 our 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 us to obtain marketing approval of and commercialize our product candidates and affect the prices we 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 our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain 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 our 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
- 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, under the current Trump administration there may be additional regulatory changes, as well as the potential repeal (in whole or in part) of the PPACA, that could negatively affect insurance coverage and/or drug prices. Any such new laws may result in additional reductions in Medicare and other healthcare funding.

We expect 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 we receive 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 us from being able to generate revenue, attain profitability, or commercialize our 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. We 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 our 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 us to more stringent product labeling and post-marketing testing and other requirements.

Laws, restrictions, and other regulatory measures are also imposed by healthcare laws and regulations in international jurisdictions and in those jurisdictions we face the same issues as in the United State regarding difficulty and cost for us to obtain marketing approval and commercialization of our product candidates and which may affect the prices we may obtain.

Governments outside the United States tend to impose strict price controls, which may adversely affect our 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, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our 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 us 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 we receive marketing approval. Our future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute the products for which we receive 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 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 our 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 our 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 our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we 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 our operations. If any of the physicians or other providers or entities with whom we expect 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.

Laws, restrictions, and other regulatory measures are also imposed by anti-kickback, fraud and abuse, and other healthcare laws and regulations in international jurisdictions and in those jurisdictions we face the same issues as in the

United State regarding exposure to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We 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 our nonclinical or clinical development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, we 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 our product candidates receives marketing approval, we 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 ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our 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 our 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 our 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 our products together with other medications.

If OP-01, OP-02, or a future product candidate receives marketing approval and we, 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 our clinical trials may indicate an apparent beneficial 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, we, 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 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 may be required to the way the product is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the 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;
- additional restrictions may be imposed on the distribution or use of the product via a Risk Evaluation and Mitigation Strategy;

- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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

We currently have no marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we 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 we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming, will require significant attention of our executive officers to manage and may nonetheless fail to effectively market and sell our product candidates. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we 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 our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we 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 we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our 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 number of companies developing or marketing treatments for AOE, including many major pharmaceutical and biotechnology companies. We expect that OP-01 will face competition from numerous FDA-approved therapeutics, including CIPRODEX® and numerous other branded and generic ear anti-infectives.

In OM, there are currently no drug therapies approved to prevent OM. We expect that OP-02 will compete primarily with a surgery where the tympanic membrane is perforated to improve drainage and ventilation of the middle ear (myringotomy or tympanostomy tube insertions) as a means of preventing recurrent or chronic OM. We may also compete with a medical device product primarily that uses a small intranasal balloon inserted into the Eustachian tube to facilitate ventilation of the Eustachian tube in patients with Eustachian tube dysfunction of a particular type. Surgery may continue to be the preferred treatment for preventing recurrent or chronic OM in children whereas the intranasal balloon may be the preferred treatment for preventing recurrent or chronic OM in adults. Neither of these competing products are used to prevent acute OM. Patients may be prescribed concurrent antibiotic therapy for acute OM, but these products will not be competitive with, but likely used in conjunction with OP-02.

Our commercial opportunity could be reduced or eliminated if our 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 we may develop. In addition, our 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 our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting nonclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our 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 us 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, our 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 our ability to market those products and decrease our 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 our product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our 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, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our 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 ours, 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 we believe 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 our product candidates. In many countries, the prices of medical products are subject to 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 we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our 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 internationally, 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 our product candidates. Increased expense is incurred to cover costs of health outcome focused research used to generate data necessary to justify the value of our products in order to secure reimbursement. We expect to experience pricing pressures in connection with the sale of any of our 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 our products.

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

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

- decreased demand for any product candidates or products that we may develop;
- injury to our 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 our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $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 we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We 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 Our Dependence on Third Parties

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

For some of our product candidates, we may in the future determine to seek to collaborate with pharmaceutical and biotechnology companies for development of products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our 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 we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential development schedule or reduce the scope of research activities, or increase our expenditures and undertake discovery or nonclinical development activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates or continue to develop our product candidates, and our business may be materially and adversely affected.

Future collaborations we 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, nonclinical or clinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery, nonclinical or clinical development for a product candidate, or repeat or conduct new discovery, and nonclinical and clinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than our products;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our 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, nonclinical or clinical development or commercialization of product candidates, might lead to additional responsibilities for us 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 our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we 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 us, if a collaborator is involved in a business combination, the collaborator might deemphasize or terminate the development of any of our product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

If our collaborations do not result in the successful development of products or product candidates, product candidates could be delayed and we may need additional resources to develop product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this periodic report also apply to the activities of our collaborators.

We contract with third parties for the manufacture of our product candidates for nonclinical and clinical studies and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.

We have utilized, and intend to continue utilizing, third parties to formulate, manufacture, package, and distribute clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have sole suppliers for one or more of our active pharmaceutical ingredients ("API"), and a different sole manufacturer for each of our 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 we believe that our third-party suppliers maintain a significant supply of APIs on hand, any sustained disruption in this supply could adversely affect our operations. We do not have any long-term agreements in place with our current API suppliers. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with regulatory requirements and our specifications. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing approved product candidates could negatively affect our sales revenues, as well as delay our clinical trials.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval. Despite drug substance and product risk management, this reliance on third parties presents a risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Any performance failure on the part of our existing or future manufacturers of drug substance or drug products could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply. If suppliers cannot supply us with our requirements, we may be required to identify alternative manufacturers, which would lead us 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 our clinical trials.

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

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are 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 our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The third parties we rely 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 our clinical or commercialization activities. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, 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 our 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 our projects, our results and development timing could suffer.

Our product candidates and any products that we 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 us.

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

Risks Related to Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the European Union, the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and internationally that are related to our 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 we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We 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 we will fail to identify patentable aspects of our discovery and nonclinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our 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 our 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 in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our 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 our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our 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 our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we 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 our 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, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without

infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our 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 our 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 our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our 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, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our own.

The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our 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. 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. In certain situations 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, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

We have acquired rights to our 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 us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we 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 us to develop our drug candidates than if we had developed the licensed technology internally.

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

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

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We 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 us 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 our confidential information could be compromised by disclosure.

We 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 our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

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

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

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

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any NDAs or similar agreements entered into by the Company may not be with all relevant parties, or adequately protect the confidentiality of our trade secrets. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we 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 our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Employee Matters, Managing Growth and Macroeconomic Conditions

Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future.

We are highly dependent on the product development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executives and key employees, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel is critical to our success. Due to the small size of the Company and the limited number of employees, each of our executives and key employees serves in a critical role. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our 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 our 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 we 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. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating drug product, nonclinical development, clinical development, regulatory strategy, and commercial strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our research and development function, as well as our corporate operations, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

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

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

Many of our employees and certain of our directors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and directors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we 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 we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are 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 our business, financial condition or results of operations.

Our 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 our business, including our 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 our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of the CROs, collaborators and third-parties on whom we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third-party collaborators. While we and, to our knowledge, our 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 our operations or our third-party collaborators, it could result in a material disruption of our drug development programs. For example, the loss of research data could delay development of our product candidates and the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. Similarly, we have no control over the security measures and computer systems of the regulatory bodies to whom we provide financial and other sensitive information. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

Risks Related to Our Common Stock

We expect our stock price to be volatile, and the market price of our common stock may drop unexpectedly.

The market price of our common stock 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 our common stock to fluctuate include:

- our ability 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 our product candidates, if approved, to achieve commercial success;
- issues in manufacturing our approved products, if any, or product candidates;
- the results of our current and any future clinical trials of our 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 our intellectual property rights or defend against the intellectual property rights of others;
- 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 our potential products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- changes in the structure of healthcare payment systems; and
- period-to-period fluctuations in our 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 our 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 our profitability and reputation.

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

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

Our executive officers, directors and principal stockholders, if they choose to act together, will have the ability to control all matters submitted to stockholders for approval.

Our executive officers and directors, combined with our principal stockholders, beneficially own shares representing approximately 81.8% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our 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 our assets. This concentration of ownership control may:

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

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

We 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. We 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 our 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 Company to obtain directors' and officers' liability insurance. As a result, it may be more difficult for the Company to attract and retain qualified individuals to serve on our board of directors or as executive officers of the Company, which may adversely affect investor confidence in the Company and could cause our business or stock price to suffer.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we will have adequate internal financial and accounting controls and procedures in place so that we 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 GAAP.

Through the fiscal year ended December 31, 2014, Otic's financial statements have been audited in accordance with generally accepted auditing standards in Israel. The consolidated financial statements for the years ended December 31, 2016 and 2015 were audited in accordance with generally accepted auditing standards in the United States.

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

Implementing any appropriate changes to our internal controls may distract the officers and employees of the 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 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 the Company are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm the stock price of the Company.

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

Provisions in our corporate charter and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the Company that stockholders may consider favorable, including transactions in which our 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 our common stock, thereby depressing the market price of our common stock. In addition, because the board of directors is responsible for appointing the members of our 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 our directors to be changed only by resolution of our 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 our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our 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 our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of the Company's charter or bylaws.

Moreover, because the Company is incorporated in Delaware, it 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 us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

We do not expect to pay any cash dividends in the foreseeable future.

We expect to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for any stockholders for the foreseeable future.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

Exhibit Index

Exhibit Number	Description
10.6	Management Continuity Agreement, dated August 7, 2017, between Novus Therapeutics, Inc. and Gregory J. Flesher. (1)
10.7	Management Continuity Agreement, dated August 7, 2017, between Novus Therapeutics, Inc. and Jon S. Kuwahara. (1)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.
(1) Incorporated by reference to Form 10-Q filed on August 9, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Novus Therapeutics, Inc.

Date: November 8, 2017

By: /s/ Gregory J. Flesher

Gregory J. Flesher
Chief Executive Officer and Director (Principal Executive Officer)

Date: November 8, 2017

By: /s/ Jon S. Kuwahara

Jon S. Kuwahara
Senior Vice President Finance & Administration (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Gregory J. Flesher, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Novus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

By: /s/ Gregory J. Flesher
Gregory J. Flesher
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Jon S. Kuwahara, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Novus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

By: /s/ Jon S. Kuwahara
Jon S. Kuwahara
Senior Vice President Finance & Administration
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Novus Therapeutics, Inc. (the "Company") for the period ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Gregory J. Flesher, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2017

By: /s/ Gregory J. Flesher
Gregory J. Flesher
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Novus Therapeutics, Inc. (the "Company") for the period ended September 30, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jon S. Kuwahara, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2017

By: /s/ Jon S. Kuwahara
Jon S. Kuwahara
Senior Vice President Finance & Administration
(Principal Financial and Accounting Officer)