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 March 31, 2019

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	NVUS	Nasdaq Capital Market

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 every Interactive Data File required to be submitted 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 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	☐	Smaller 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 May 10, 2019, there were 12,896,473 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 MARCH 31, 2019

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2019 (Unaudited)	December 31, 2018 (Note 2)
ASSETS		
Current assets:		
Cash	$ 9,056	$ 12,972
Prepaid expenses and other current assets	1,265	1,304
Total current assets	10,321	14,276
Property and equipment, net	12	14
Operating lease asset, net	446	—
Goodwill	1,867	1,867
Other assets	805	869
Total assets	$ 13,451	$ 17,026
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 480	$ 689
Current operating lease liability	170	—
Accrued expenses and other liabilities	2,591	1,845
Total current liabilities	3,241	2,534
Non-current operating lease liability	281	—
Total liabilities	3,522	2,534
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2019 and December 31, 2018; 9,447,361 and 9,422,143 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	9	9
Additional paid-in capital	56,372	56,054
Accumulated deficit	(46,452)	(41,571)
Total stockholders' equity	9,929	14,492
Total liabilities and stockholders' equity	$ 13,451	$ 17,026

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)
(Unaudited)

	For the Three Months Ended March 31,	
	2019	2018
Operating expenses		
Research and development	$ 2,989	$ 1,097
General and administrative	1,886	1,698
Total operating expenses	4,875	2,795
Loss from operations	(4,875)	(2,795)
Other income (expense), net	(6)	(11)
Net loss and comprehensive loss	$ (4,881)	$ (2,806)
Net loss per share, basic and diluted	$ (0.52)	$ (0.36)
Weighted-average common shares outstanding, basic and diluted	9,427,073	7,749,263

See accompanying notes to unaudited condensed consolidated financial statements.

NOVUS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Stockholders' Equity						
	Common Stock		Preferred Stock				
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance as of December 31, 2018	9,422,143	$ 9	—	$ —	$ 56,054	$ (41,571)	$ 14,492
Issuance of common stock at-the-market, net of issuance costs	25,218	—	—	—	107	—	107
Stock-based compensation	—	—	—	—	211	—	211
Net loss and other comprehensive loss	—	—	—	—	—	(4,881)	(4,881)
Balance as of March 31, 2019	9,447,361	$ 9	—	$ —	$ 56,372	$ (46,452)	$ 9,929
Balance as of December 31, 2017	7,110,414	$ 7	—	$ —	$ 46,951	$ (27,506)	$ 19,452
Issuance of common stock at-the-market, net of issuance costs	2,296,610	2	—	—	7,489	—	7,491
Stock-based compensation	—	—	—	—	161	—	161
Net loss and other comprehensive loss	—	—	—	—	—	(2,806)	(2,806)
Balance as of March 31, 2018	9,407,024	$ 9	—	$ —	$ 54,601	$ (30,312)	$ 24,298

See accompanying notes to unaudited condensed consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2019	2018
Operating activities		
Net loss	$ (4,881)	$ (2,806)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2	3
Amortization of operating lease asset	43	—
Stock-based compensation	211	161
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	103	192
Accounts payable and accrued expenses	537	179
Operating lease liability	(38)	
Net cash used in operating activities	(4,023)	(2,271)
Investing activities		
Net cash provided by investing activities	—	—
Financing activities		
Proceeds from issuance of common stock, net	107	7,491
Net cash provided by financing activities	107	7,491
Net (decrease) increase in cash	(3,916)	5,220
Cash at beginning of period	12,972	17,303
Cash at end of period	$ 9,056	$ 22,523

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1. Description of Business

Novus Therapeutics is a specialty pharmaceutical company focused on developing products for disorders of the ear, nose, and throat ("ENT"). Unless otherwise indicated, references to the terms "Novus" or the "Company", refer to Novus Therapeutics, Inc.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("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. Pursuant to these rules and regulations, 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 Novus for the year ended December 31, 2018 included in the Annual Report on Form 10-K filed by the Company with the SEC on March 28, 2019, as amended. The results of operations and comprehensive loss for the three months ended March 31, 2019 are not necessarily indicative of results expected for the full fiscal year or any other future period.

Principles of Consolidation

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"). Otic owns 100% of the issued and outstanding common stock or other ownership interest in its U.S. subsidiary, Otic Pharma, Inc.

The functional currency of the Company's foreign subsidiary is the U.S. Dollar; however, certain expenses, assets and liabilities are transacted at the local currency. These transactions are translated from the local currency into U.S. Dollars at exchange rates during or at the end of the reporting period.

All significant intercompany accounts and transactions among the entities have been eliminated from the condensed consolidated financial statements.

Liquidity and Financial Condition

The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company recorded a net loss of $4.9 million for the three months ended March 31, 2019. As of March 31, 2019, the Company had cash of $9.1 million, working capital of $7.1 million and an accumulated deficit of $46.5 million. 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. On April 30, 2019, the Company raised $10.7 million in a registered direct offering, see Note 8. Subsequent Events.

Adequate additional funding may not be available to us on acceptable terms on a timely basis, or at all. The Company has implemented, and will continue to implement, certain cost cutting measures commencing in the first half of 2019 to reduce its cash flow requirements. Consistent with the actions the Company has taken in the past, it will execute the appropriate steps to enable the continued operations of the business and preservation of the value of its assets beyond the next twelve months, including but not limited to actions such as reduced personnel-related costs, delay or curtailment of the Company's research and development activities, and other discretionary expenses that are within the Company's control. These initiatives, if required, may have an adverse impact on the Company's ability to achieve certain of its planned objectives during 2019 as it seeks strategic alternatives.

At the time of issuance of the condensed consolidated financial statements for the period ended March 31, 2019, the Company concluded that there is substantial doubt regarding the Company's ability to continue as a going concern for the twelve months from the date of issuance of the condensed consolidated financial statements. The financial information and the condensed consolidated financial statements included in this filing have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. This financial information and these financial statements do not include any adjustments that may result from an unfavorable outcome of this uncertainty. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations

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 unaudited condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's financial statements relate to stock-based compensation, accruals for liabilities, operating lease liability, carrying value of goodwill, 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 condensed consolidated financial statements.

Cash and Cash Equivalents

Cash represents cash deposits held at financial institutions. The Company considers all liquid investments purchased with an original maturity of three months or less and that can be liquidated without prior notice or penalty to be cash equivalents. Cash equivalents are held for the purpose of meeting short-term liquidity requirements, rather than for investment purposes. The Company had no cash equivalents or restricted cash at March 31, 2019 and December 31, 2018.

Concentration of Credit Risk and Other Risks and Uncertainties

As of March 31, 2019 and December 31, 2018, all of the Company's long-lived assets were located in the U.S.

Financial instruments that are subject to concentration of credit risk consist primarily of cash equivalents. The Company's policy is to invest cash in institutional money market funds to limit the amount of credit exposure. At times, the Company maintains cash equivalents in short-term money market funds and it has not experienced any losses on its cash equivalents.

The Company's products will require approval from the U.S. Food and Drug Administration ("FDA") and foreign regulatory agencies before commercial sales can commence. There can be no assurance that its products will receive any of these required approvals. The denial or delay of such approvals may impact the Company's business in the future.

The Company is subject to risks common to companies in the pharmaceutical industry, including, but not limited to, new technological innovations, clinical development risk, establishment of appropriate commercial partnerships, protection of proprietary technology, compliance with government and environmental regulations, uncertainty of market acceptance of products, product liability, the volatility of its stock price and the need to obtain additional financing.

Reportable Segments

Operating segments under GAAP are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. The CODM is the Company's Chief Executive Officer and the Company has determined that it operates in one business segment, which is developing products for disorders of the ear, nose, and throat.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the assets acquired and liabilities assumed under the acquisition method of accounting. Goodwill is not amortized but is evaluated for impairment annually as of October 1st or if indicators of impairment exist that would, more likely than not, reduce the fair value from its carrying amount. The Company determined that no impairment existed as of March 31, 2019 and December 31, 2018.

Long-Lived Assets

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Additions, major renewals and improvements are capitalized and repair and maintenance costs are charged to expense as incurred. Leasehold improvements are amortized over the remaining life of the initial lease term or the estimated useful lives of the assets, whichever is shorter.

The carrying value of long-lived assets, including operating lease right-of-use assets and intangible assets, is evaluated whenever events or changes in business circumstances or the Company's planned use of long-lived assets indicate, based on undiscounted future operating cash flows, that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. When an indicator of impairment exists, undiscounted future operating cash flows of long-lived assets are compared to their respective carrying value. If the carrying value is greater than the undiscounted future operating cash flows of long-lived assets, the long-lived assets are written down to their respective fair values and an impairment loss is recorded. Fair value is determined primarily using the discounted cash flows expected to be generated from the use of assets. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected cash flows. No impairments of tangible assets have been identified during the periods presented.

Research and Development Expenses

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under contracts with third parties may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

The Company's contracts with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to its vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. The Company's accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. These contracts may be terminated by the Company upon written notice and the Company is generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances the Company may be further responsible for termination fees and penalties. The Company estimates its research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company's prior-period accrued estimates for clinical trial activities through March 31, 2019.

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, stock options, warrants and restricted stock units 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.

	For the Three Months Ended March 31,	
	2019	2018
	(In thousands, except share and per share data)	
Net loss used in the calculation of basic and diluted loss per share	$ (4,881)	$ (2,806)
Net loss per share, basic and diluted	$ (0.52)	$ (0.36)
Weighted-average number of common shares, basic and diluted	9,427,073	7,749,263

The computation of diluted earnings per share excludes stock options, warrants, and restricted stock units that are anti-dilutive. For the three months ended March 31, 2019, common share equivalents of 1,241,717 shares were anti-dilutive. For the three months ended March 31, 2018, common share equivalents of 816,766 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 fair value of stock options is determined using the Black-Scholes option pricing model, using assumptions which are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical industry. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determined the expected life assumption using the simplified method, which is an average of the options ordinary vesting period and the contractual term. The expected dividend assumption was based on the Company's history and expectation of dividend payouts. The Company has not paid and does not expect to pay dividends at any time in the foreseeable future. The Company recognizes forfeitures on an actual basis and as such did not estimate forfeitures to calculate stock-based compensation.

Effective as of August 1, 2018, the Board of Directors amended the Company's 2014 Stock Incentive Plan (the "2014 Plan") and the Company's 2014 Employee Stock Purchase Plan (the "ESPP" and, together with the 2014 Plan, the "Plans") to reduce the share reserves under the Plans. These reductions were made to equitably adjust the share reserves in accordance with the terms of the Plans. As a result of these equitable adjustments: (1) the number of shares of common stock authorized for issuance under the 2014 Plan (excluding shares underlying outstanding awards as of August 1, 2018) was reduced to 766,500 shares and the maximum number of shares that can be added to the 2014 Plan under evergreen provision set forth in Section 4(a)(1)(C) of the 2014 Plan was reduced to 550,000 shares annually; and (2) the number of shares of common stock authorized for future issuance under the ESPP was reduced to 209,500 shares (excluding shares previously issued under the ESPP prior to August 1, 2018) and the maximum number of shares that can be added to the ESPP under the evergreen provision set forth in the ESPP was reduced to 135,000 shares annually. The 2014 Plan and ESPP were amended and restated as of August 1, 2018 to reflect these equitable adjustments. The number of shares reserved for issuance under the 2014 Plan and ESPP was increased by 376,885 and 94,221 shares, respectively, effective as of March 31, 2019.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the estimated fair value of the stock options on grant date, determined using the Black-Scholes option pricing model. The awards generally vest over the period the Company expects to receive services from nonemployees. Similar to stock options granted to employees, the fair value of stock options granted nonemployees, determined using the Black-Scholes option pricing model, involves assumptions that are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical industry. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior on stock options granted to nonemployees, the Company determined the contractual term is the appropriate periods for expected life on stock options granted to nonemployees. The expected dividend assumption was based on the Company's history and expectation of dividend payouts. The Company has not paid and does not expect to pay dividends at any time in the foreseeable future. The Company recognizes forfeitures on an actual basis and as such did not estimate forfeitures to calculate stock-based compensation.

Income Taxes

The Company's policy related to accounting for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As of December 31, 2018, there are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the Company's effective tax rate, and the Company has noted no material changes through March 31, 2019. The Company has not recognized interest and penalties in the balance sheets or statements of operations and comprehensive loss. The Company is subject to tax in the U.S., Israel and California.

Recently Issued Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 currently assessing the impact and timing of adopting this guidance on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *"Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement"*, an amendment to the accounting guidance on fair value measurements. The guidance modifies the disclosure requirements on fair value measurements, including the removal of disclosures of the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. The guidance also adds certain disclosure requirements related to Level 3 fair value measurements. The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company does not expect the adoption of this guidance will have a material impact on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, an amendment to the accounting guidance on cloud computing service arrangements that changes the accounting for implementation costs incurred in a cloud computing arrangement that is a service contract. The update aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance also requires an entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The guidance is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is currently evaluating the impact the guidance will have on its condensed consolidated financial statements.

Recently Adopted Accounting Pronouncements

On January 1, 2019, the Company adopted ASU 2016-02, *Leases (Topic 842)* along with related clarifications and improvements. This pronouncement requires lessees to recognize a liability for lease obligations with lease terms greater than twelve months, which represents the discounted obligation to make future lease payments, and a corresponding right-of-use asset on the balance sheet. The guidance also changes the definition of a lease and expands required disclosures of key information about leasing arrangements that is intended to give financial statement users the ability to assess the amount, timing, and potential uncertainty of cash flows related to leases. The Company elected the optional transition method to apply the standard as of the effective date and therefore, did not restate prior periods to apply the standard to the comparative periods presented on our condensed consolidated financial statements.

The Company elected practical expedients as follows as of January 1, 2019:

Practical expedient package	The Company has not reassessed whether any expired or existing contracts are, or contain, leases.
	The Company has not reassessed the lease classification for any expired or existing leases.
	The Company has not reassessed initial direct costs for any expired or existing leases.
Hindsight practical expedient	The Company has not elected the hindsight practical expedient, which permits the use of hindsight when determining lease term and impairment of operating lease assets.

As a result of adopting ASC 842 as of January 1, 2019, the Company recorded an operating lease right-of-use asset of $489,000 and related operating lease liability of $491,000, respectively, primarily related to the Company's office lease, based on the present value of the future lease payments on the date of adoption.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement—Reporting Comprehensive Income (Topic 220)*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the passing of H.R. 1/Public Law No. 115-97, commonly known as the Tax Cuts and Jobs Act (the "Act") and requires certain disclosures about stranded tax effects. The amendments in ASU No. 2018-02 are effective beginning in 2019, with early adoption permitted, and may be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate tax rate in the Act is recognized. The Company adopted the guidance effective January 1, 2019. There was no impact upon adoption.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 *Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU No. 2018-07 supersedes Subtopic 505-50 *Equity—Equity-Based Payments to Non-Employees*. The amendments in ASU No. 2018-07 are effective for the Company beginning in 2020, with early adoption permitted, but no earlier than a company's adoption date of Topic 606 *Revenue from Contracts with Customers*. The Company has applied this guidance to its condensed consolidated financial statements and related disclosures beginning the first quarter of 2019. There was no material impact upon adoption.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification (the "SEC Release"), to eliminate or modify certain disclosure rules that are redundant, outdated, or duplicative of GAAP or other regulatory requirements. Among other changes, the SEC Release expanded the disclosure rules to require inclusion of an analysis of changes in stockholders' equity in a company's interim condensed consolidated financial statements. Presentation of the changes in each caption of stockholders' equity presented on the condensed consolidated balance sheets must be provided in a note or separate statement, and the Company has elected to include a separate statement (the Condensed Consolidated Statements of Stockholders' Equity above) to present activity during the three months ended March 31, 2019 and March 31, 2018.

No other new accounting pronouncement issued or effective during the fiscal period had or is expected to have a material impact on the Company's condensed consolidated financial statements or disclosures.

Note 3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other assets consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Prepaid insurance	$ 325	$ 413
Prepaid other	166	261
Insurance receivable	747	583
Other current assets	27	47
Total prepaid expenses and other current assets	$ 1,265	$ 1,304

Note 4. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Accrued clinical	$ 1,273	$ 735
Accrued professional services	261	194
Accrued vacation	188	160
Accrued compensation and related expenses	805	742
Accrued other	64	14
Total accrued expenses and other liabilities	$ 2,591	$ 1,845

Note 5. Commitments and Contingencies

Operating Leases

The Company leases office space under a single operating lease. Total rental expense for all operating leases in the accompanying condensed consolidated statements of operations and comprehensive loss was $49,000 and $42,000 for the three months ended March 31, 2019 and 2018, respectively.

In September 2015, the Company entered into a three-year operating lease for 5,197 square feet of office space in Irvine, California. The lease had an expiration date of August 31, 2018; however, the Company extended the term of the lease through September 30, 2021 by amending the office lease effective October 31, 2018.

The Company determines if a contract contains a lease at inception. Our material operating lease consist of a single office space. Our office lease has remaining terms of 2.75 years and does not include options to extend the lease for additional periods.

Operating lease assets and liabilities are recognized at the lease commencement date. Operating lease liabilities represent the present value of lease payments not yet paid. Operating lease assets represent our right to use an underlying asset and are based upon the operating lease liabilities adjusted for prepayments or accrued lease payments, initial direct costs, lease incentives, and impairment of operating lease assets. To determine the present value of lease payments not yet paid, we estimate incremental secured borrowing rates corresponding to the maturities of the leases. As we have no outstanding debt nor committed credit facilities, secured or otherwise, we estimate this rate based on prevailing financial market conditions, comparable company and credit analysis, and management judgment.

Our leases typically contain rent escalations over the lease term. We recognize expense for these leases on a straight-line basis over the lease term. Additionally, tenant incentives used to fund leasehold improvements are recognized when earned and reduce our right-of-use asset related to the lease. These are amortized through the right-of-use asset as reductions of expense over the lease term. Our lease agreement does not contain any material residual value guarantees or material restrictive covenants. The Company has no lease agreements with lease and non-lease components.

Related to the adoption of Topic 842, our policy elections were as follows:

Separation of lease and non-lease components	While we do not currently have any lease agreement with lease and non-lease components, we elected this expedient to account for lease and non-lease components as separate components.

Short-term policy

We have elected the short-term lease recognition exemption for all applicable classes of underlying assets. Short-term disclosures include only those leases with a term greater than one month and 12 months or less, and expense is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or
less, that do not include an option to purchase the underlying asset that we are reasonably certain to exercise, are not recorded on the balance sheet.

The components of lease expense were as follows:

	Three Months Ended March 31, 2019
Operating lease cost[a]	$ 49

[a] Includes variable operating lease expenses, which is immaterial

Other information related to leases was as follows (in thousands, except lease term and discount rate):

	Three Months Ended March 31, 2019
Supplemental Cash Flows Information	
Cash paid for amounts included in the measurement of lease liability:	
Operating cash flows from operating lease	$ 45
Operating lease asset obtained in exchange for lease obligation:	
Operating lease	446
Remaining lease term	
Operating lease	2.5 years
Discount rate	
Operating lease	3.25%

Future payments under noncancelable extended operating leases having initial or remaining terms of one year or more are as follows for the remaining fiscal year and thereafter (in thousands):

2019 (remainder of)	$ 136
2020	188
2021	146
Total minimum lease payments	470
Less imputed interest	(20)
Present value of lease liabilities	$ 450

Grants and Licenses

Israeli Innovation Authority Grant

From 2012 through 2015, the Company received grants in the amount of approximately $537,000 from the Israeli Innovation Authority (previously 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. Repayment of the grant is contingent upon the successful completion of the Company's research and development programs and generating sales. The Company has no obligation to repay these grants, if the research and development program fails, is unsuccessful or aborted or if no sales are generated. The Company had not yet generated sales as of March 31, 2019; therefore, no liability was recorded for the repayment in the accompanying condensed consolidated financial statements.

Otodyne License Agreement

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 exclusive worldwide rights to develop and commercialize OP0201, 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 ("ETD"). 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 $750,000 and issued 9,780 common shares to the Licensors, which was expensed to research and development during the year ended December 31, 2015.

In December 2015, the Licensors completed transfer of all technology, including the active Investigational New Drug application to the Company. The Company is obligated to pay up to $42.1 million in development and regulatory milestones if OP0201 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 made a $300,000 milestone payment in March 2019 related to the first patient enrolled in a phase 2 study. There were no milestones achieved during the year ended December 31, 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 does not consider a liability probable and 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

On September 22, 2014, Tokai Pharmaceuticals, Inc. ("Tokai"), the legal predecessor of the Company, completed the initial public offering of its common stock (the "IPO"). Subsequent to the IPO, several lawsuits were filed against Tokai, Jodie P. 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 (the "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. The Company intends to vigorously defend against these claims. 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, the Company is unable to predict the ultimate outcome of these actions, and therefore it 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. On May 24, 2018, the plaintiff dismissed its complaint in the Superior Court of the State of California and refiled its complaint in the Business Litigation Session of the Superior Court Department of the Suffolk County Trial Court, Massachusetts ("Massachusetts State Court"). On June 28, 2018, plaintiff Wu moved to consolidate the Jackie888 Action with the Wu Action (discussed below). On June 29, 2018, plaintiffs Jackie888 and Wu filed a consolidated complaint. On July 6, 2018, the Jackie888 Action was consolidated with the Wu Action. Events following consolidation are discussed below.

- Wu Action. On December 5, 2016, a putative securities class action was filed in the 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. 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. On March 20, 2018, the United States Supreme Court ruled in Cyan that state courts have subject matter jurisdiction over covered class actions alleging only Securities Act claims and that such actions are not removable to federal court. On March 22, 2018, plaintiff moved for leave to submit the Cyan decision in support of plaintiff's remand motion. On March 27, 2018 the Wu Action was remanded to the Massachusetts State Court. On May 3, 2018, plaintiff filed an amended class action complaint. Following the refiling of the Jackie888 Action in Massachusetts State Court (discussed above), on June 28, 2018, plaintiff Wu moved to consolidate the Jackie888 Action with the Wu Action. On June 29, 2018, plaintiffs Jackie888 and Wu filed a consolidated complaint. On July 6, 2018, the Jackie888 Action was consolidated with the Wu Action. Defendants moved to dismiss the consolidated complaint on August 15, 2018, plaintiffs filed their opposition thereto on September 28, 2018, and defendants filed their reply in support of their motion on October 19, 2018. In addition, Defendants moved to strike the class allegations in the consolidated complaint on August 15, 2018, plaintiffs filed their opposition thereto on September 11, 2018, and defendants filed their reply in support of their motion on September 21, 2018. The court held a hearing on November 15, 2018 on defendants' motion to strike. On December 20, 2018, the court denied defendants' motion to strike. The court held a hearing on December 20, 2018 on defendants' motion to dismiss. On January 8, 2019, the court denied defendants' motion to dismiss. On February 6, 2019, the court entered a scheduling order, pursuant to which discovery on merits issues was stayed pending the court's resolution of class certification. On April 18, 2019, the court held a hearing as to plaintiff Wu's failure to respond to defendant's discovery requests. The court issued an order requiring plaintiff Wu to serve written responses to the pending discovery requests by May 10, 2019. According to the order, if plaintiff Wu fails to do so, her individual action will be subject to dismissal with prejudice. Discovery on class certification and standing issues must be completed by July 12, 2019. Plaintiffs' motion for class certification and defendants; motion to dismiss for lack of standing shall be filed on or by August 22, 2019, oppositions thereto shall be filed on or by September 19, 2019, and replies in support shall be filed on or by October 10, 2019. The court scheduled a hearing for October 23, 2019 on the motions.
- 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. On September 7, 2018, plaintiff filed an amended complaint. Defendants moved to dismiss the amended complaint on October 15, 2018. Plaintiff opposed defendants' motion by November 19, 2018, defendants filed a reply in support of their motion by December 17, 2018, and plaintiff filed a sur-reply in support of his opposition by January 8, 2019. The court set a hearing for February 25, 2019 on defendants' motion to dismiss but later cancelled the hearing. At this time, the hearing has not been rescheduled.

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 March 31, 2019.

Note 6. 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 23% in the year 2018 and is expected to be subject to an Israeli corporate tax rate of 23% in the year

2019 and thereafter. The Company was subject to a blended U.S. tax rate (federal as well as state corporate tax) of 21% in 2018 and is expected to be subject to a blended U.S. tax rate of 21% in 2019.

Note 7. Stockholders' Equity

Equity Distribution Agreement

On July 23, 2018, the Company filed a prospectus supplement (the "2018 Prospectus") under which the Company may offer and sell, from time to time, pursuant to an equity distribution agreement with Piper Jaffray & Co., up to $9.8 million in shares of its common stock. 25,218 shares have been sold under the 2018 Prospectus for gross proceeds of approximately $110,000 as of March 31, 2019.

Note 8. Subsequent Events

On April 30, 2019, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate 3,449,112 shares of its common stock for gross proceeds of approximately $10.7 million under its effective shelf registration statement on Form S-3 (File No. 333-226286), which became effective on July 31, 2018. In a concurrent private placement, the Company also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 3,449,112 shares of its common stock at an exercise price of $4.00 with a term of eighteen months and Series B warrants to purchase up 3,449,112 shares of its common stock at an exercise price of $4.00 with a term of five years. The Series B warrants become exercisable only upon the exercise of the Series A warrants.

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

The unaudited 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, 2018 included in the Annual Report on Form 10-K filed by the Company with the SEC on March 28, 2019, as amended. 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. Unless otherwise indicated, references to the terms "Novus", the "Company", "we", "our" and "us" refer to Novus Therapeutics, Inc. References to the term "Tokai" refer to Tokai Pharmaceuticals, Inc., the legal predecessor of the Company.

ABOUT NOVUS THERAPEUTICS

Overview

Novus Therapeutics, Inc. is a specialty pharmaceutical company focused on developing products for patients with disorders of the ear, nose, and throat ("ENT"). The Company has two platform technologies, each with the potential to be developed for multiple indications. Novus' lead program (OP0201) is a surfactant-based nasal aerosol drug-device combination product candidate being developed as a potential first-in-class treatment option for patients at risk for, or with, otitis media ("OM"), which is middle ear inflammation and effusion with or without infection. Globally, OM affects more than 700 million adults and children every year, with over half of the cases occurring in children under five years of age. OM is one of the most common disorders seen in pediatric practice, and in the U.S. is a leading cause of health care visits and the most frequent reason children are prescribed antibiotics or undergo surgery. Novus also has a foam-based drug delivery technology platform (OP01xx), which may be developed in the future to deliver drugs into the ear, nasal, and sinus cavities.

Surfactant Platform (OP02xx)

The first product in the surfactant platform program, OP0201, is being developed as a potential first-in-class treatment option for OM. OM is often caused by Eustachian tube dysfunction ("ETD"). OP0201 is a nasal aerosol, drug-device combination product comprised of a novel formulation of a surfactant (dipalmitoylphosphatidylcholine ["DPPC"]) and a spreading agent (cholesteryl palmitate ["CP"]) suspended in propellant. The product is administered intranasally via a pressurized metered-dose inhaler ("pMDI"). OP0201is intended to be used to restore the normal physiologic activity of the Eustachian tube ("ET"), which is a small tube that connects from the chamber of the middle ear to the back of the nasopharynx. Together, the active ingredients in OP0201 effectively absorb to the air-liquid interface of the mucosa and reduce the interfacial surface tension of the ET, which reduces passive pressure required for the ET to open. In other words, OP0201 promotes 'de-sticking' of the ET so that ventilation of the middle ear is restored.

Novus has completed three phase 1 placebo-controlled clinical trials in adults that were designed to evaluate safety and tolerability of single and repeated intranasal does of OP0201. Results of two single-dose phase 1 clinical trials demonstrated safety and tolerability of OP0201 nasal aerosol in both healthy adults (study C-001) and in adults with acute otitis media (study C-004). The Company also completed enrollment of a 14-day phase 1 clinical trial in healthy adults (study C-002). In addition, Novus is currently conducting an exploratory phase 2a clinical trial of OP0201 nasal aerosol in infants and children with acute otitis media (study C-006). Upon completion of the phase 2a study, Novus intends to initiate phase 2 and phase 3 studies with an initial focus on a development program that, if successful, will lead to registration of OP0201 nasal aerosol in North America and key European markets as a product to treat OM and prevent OM in infants and children. Additional development activities to support registration of OP0201 nasal aerosol in other countries, or for other indications, or other patient populations, may occur in the future.

Foam Platform (OP01xx)

OP0101 and OP0102 are foam-based products intended to be used as a delivery vehicle for drugs to be administered into the ear canals, as well as the nasal and sinus cavities. OP0101 was the initial product utilizing the foam platform. It was developed as an improved treatment option for acute otitis externa ("AOE"), a common infectious medical condition of the outer ear canal that affects tens of millions of adults and children each year (frequently called "swimmer's ear"). Novus completed four clinical trials of OP0101 in 353 adult and pediatric subjects, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP0101 that was non-inferior to standard of care, but with a more favorable dosing regimen (dose daily instead of two doses daily for seven days).

In 2016, Novus began development of OP0102, a second-generation formulation designed to rapidly relieve ear pain (an unmet need in AOE) and eradicate infection with less than seven days of treatment. Novus subsequently suspended the OP0102 development program to focus resources on the surfactant program.

RECENT DEVELOPMENTS

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. Piper Jaffray sold 2,463,966 shares of the Company's common stock under the Equity Distribution Agreement through March 9, 2018, resulting in total proceeds of approximately $8.5 million.

On July 23, 2018, the Company filed a prospectus supplement (the "2018 Prospectus") under which the Company may offer and sell, from time to time, through Piper Jaffray, up to $9.8 million in shares of its common stock. Piper Jaffray sold 25,218 shares of the Company's common stock under the 2018 Prospectus through March 31, 2019.

2019 Equity Offering

On April 30, 2019, following the end of the first quarter of 2019, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate 3,449,112 shares of its common stock for gross proceeds of approximately $10.7 million under its effective shelf registration statement on Form S-3 (File No. 333-226286), which became effective on July 31, 2018. In a concurrent private placement, the Company also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 3,449,112 shares of its common stock at an exercise price of $4.00 with a term of eighteen months and Series B warrants to purchase up 3,449,112 shares of its common stock at an exercise price of $4.00 with a term of five years. The Series B warrants become exercisable only upon the exercise of the Series A warrants.

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 accounting principles generally accepted in the U.S. ("GAAP"). The preparation of these financial statements requires 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 months ended March 31, 2019, as compared to those disclosed in the Annual Report on Form 10-K for the year ended December 31, 2018 filed by the Company with the SEC on March 28, 2019, as amended.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2019 and 2018

The following table provides comparative unaudited results of operations for the three months ended March 31, 2019 and 2018 (in thousands):

	For the Three Months Ended March 31, 2019	2018	$ Variance	% Variance
Operating expenses:				
Research and Development	$ 2,989	$ 1,097	1,892	172%
General and Administrative	1,886	1,698	188	11%
Total operating expenses	4,875	2,795	2,080	74%
Loss from operations	(4,875)	(2,795)	(2,080)	74%
Other income (expense), net	(6)	(11)	5	(45)%
Net loss	$ (4,881)	$ (2,806)	(2,075)	74%

Research and Development Expenses

The increase in research and development expenses of $1.9 million for the three months ended March 31, 2019 compared to the three months ended March 31, 2018, was primarily due to an increase in clinical related costs for OP0201 of $1.6 million, an increase in formulation development costs for OP0201 of $266,000, and an increase in personnel related costs of $189,000 related to the hiring of additional employees in clinical operations. The increases were partially offset by a decrease in consulting costs of $171,000 as more work was performed in-house. We expect research and development expenses to increase in subsequent periods as we advance our OP0201 program.

General and Administrative Expenses

The increase in general and administrative expenses of $188,000 for the three months ended March 31, 2019 compared to the three months ended March 31, 2018 was primarily due to an increase of $162,000 in personnel related costs and an increase in stock-based compensation expense of $45,000. Additionally, litigation costs related to Tokai shareholder lawsuits increased by $110,000. These increases were partially offset by a decrease of $138,000 in other general and administrative costs.

Other Income (Expense), Net

The change in other income (expense), net was primarily related to a decrease of $9,000 in value added tax ("VAT") paid in Israel, partially offset by an increase of $4,000 in realized gains on foreign currency translation for the three months ended March 31, 2019. During the same period in 2018, the Company had other expense of $11,000, net.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2019, we had cash of $9.1 million, consisting of readily available cash in bank accounts. While we believe our cash is not subject to excessive risk, we maintain significant amounts of cash at one or more financial institutions that are in excess of federally insured limits. 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 a 2017 reverse merger with Tokai. We have concluded and disclosed in the footnotes to our unaudited condensed consolidated financial statements, included elsewhere within this Quarterly Report on Form 10-Q, that we do not have sufficient cash to fund our operations through 12 months from the date of issuance of the most recent financial statements.

We do not have any approved products for commercial sale and have never generated revenue from product sales, and have incurred significant net losses since our inception and expect to continue to incur net operating losses for the foreseeable future. We do not expect to receive any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our product candidates or enter into collaborative arrangements with third parties. Our primary use of cash is to fund operating expenses, which consist of research and development expenses and general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay or prepay these expenses. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development 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.

We will continue to require additional financing in order to advance OP0201 through clinical development, to manufacture, obtain regulatory approval for and to commercialize our product candidates, to develop, acquire or in-license other potential product candidates, and to fund operations for the foreseeable future. Therefore, we will seek to raise additional capital through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Adequate additional funding may not be available to us on acceptable terms on a timely basis, or at all. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, and may cause us to delay the scope of or suspend one or more of our clinical trials, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Please see Part II, Item 1A. *Risk Factors* for additional risks associated with our substantial capital requirements and the challenges we may face in raising capital.

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 third quarter of 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 and filed a related prospectus supplement (the "2017 Prospectus"). On July 23, 2018, the Company filed a new prospectus supplement (the "2018 Prospectus"). Under the 2017 Prospectus, we sold shares of common stock from October 2, 2017 through March 9, 2018 for gross proceeds of approximately $8.5 million. Under the 2018 Prospectus, we may offer and sell up to an additional $9.8 million in shares of common stock. 25,218 shares have been sold under the 2018 Prospectus for gross proceeds of approximately $110,000 as of March 31, 2019. 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.

On April 30, 2019, following the end of the first quarter of 2019, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company agreed to sell, in a registered direct offering, an aggregate 3,449,112 shares of its common stock for gross proceeds of approximately $10.7 million under its effective shelf registration statement on Form S-3 (File No. 333-226286), which became effective on July 31, 2018. In a concurrent private placement, the Company also agreed pursuant to the securities purchase agreement to issue to such investors Series A warrants to purchase up to 3,449,112 shares of its common stock at an exercise price of $4.00 with a term of eighteen months and Series B warrants to purchase up 3,449,112 shares of its common stock at an exercise price of $4.00 with a term of five years. The Series B warrants become exercisable only upon the exercise of the Series A warrants.

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.

As a result of these conditions, we have concluded that substantial doubt about our ability to continue as a going concern exists as conditions and events, considered in the aggregate, indicate that it is probable that we will be unable to meet our obligations as they become due within one year after the date that our condensed consolidated financial statements were issued without raising additional capital. The financial information and condensed consolidated financial statements included in this filing have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. This financial information and these financial statements do not include any adjustments that may result from an unfavorable outcome of this uncertainty. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

Cash Flows

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

	For the Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	$ (4,023)	$ (2,271)
Net cash used in investing activities	—	—
Net cash provided by financing activities	107	7,491
Net increase in cash and restricted cash	$ (3,916)	$ 5,220

Comparison of the Three Months Ended March 31, 2019 and 2018

Net cash used in operating activities for the three months ended March 31, 2019 consisted primarily of our net loss of $4.9 million, partially offset by non-cash items consisting primarily of stock-based compensation, and depreciation and amortization totaling $256,000. Additionally, cash used in operating activities for the three months ended March 31, 2019 reflected a net increase in cash from changes in operating assets and liabilities of $602,000, primarily due to a decrease in our prepaid expenses and an increase in our other accrued expenses, partially offset by a decrease in our accounts payable.

Net cash used in operating activities for the three months ended March 31, 2018 consisted primarily of our net loss of $2.8 million, partially offset by non-cash items consisting of depreciation and stock-based compensation totaling $164,000. Additionally, cash used in operating activities for the three months ended March 31, 2018 reflected a net increase in cash from changes in operating assets and liabilities of $371,000, primarily due to a decrease in our prepaid expenses and increases in accounts payable and certain other accrued liabilities, partially offset by a decrease in accrued severance expenses.

There was no cash provided by or used in the Company's investing activities for the three months ended March 31, 2019 and 2018.

Net cash provided by financing activities for the three months ended March 31, 2019 was comprised of $107,000 in net proceeds from the 2018 Prospectus for the sale of approximately 25,000 shares of Novus common stock.

Net cash provided by financing activities for the three months ended March 31, 2018 was comprised of $7.5 million in net proceeds from the Equity Distribution Agreement for the sale of approximately 2.3 million shares of Novus common stock.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

Contractual Arrangements

No material changes to contractual obligations and commitments occurred during the three months ended March 31, 2019.

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.

Per §229.305 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in §229.10(f)(1) of Regulation S-K, is not required to provide the disclosure required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of March 31, 2019, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, management concluded that our disclosure controls and procedures were effective in alerting them in a timely manner to material information required to be disclosed in our periodic reports filed with the SEC.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) during the quarter ended March 31, 2019 that have materially affected, or are 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 under the heading "Legal Proceedings" in Note 5, 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 "Novus", the "Company", "we", "our", and "us" refer to Novus Therapeutics, Inc.

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.

The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company recorded a net loss of $4.9 million for the three months ended March 31, 2019. As of March 31, 2019, the Company had cash of $9.1 million, working capital of $7.1 million and an accumulated deficit of $46.5 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We expect it will be several years, if ever, before we have a product candidate ready for commercialization. We have financed our operations to date primarily through sales of equity. We have devoted substantially all of our financial resources and efforts to research and development, including pre-clinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year and will depend, in part, on the rate at which we incur expenses and our ability to generate revenue. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We are currently focused on developing OP0201 nasal aerosol 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). Although we have successfully manufactured several current Good Manufacturing Procedures ("cGMP") batches of OP0201 nasal aerosol drug product suitable for clinical trials, these batches were all of a smaller scale, and we may have difficultly scaling up manufacturing in a timely and cost-effective manner. We have completed three phase 1 placebo-controlled clinical trials in adults that were designed to evaluate safety and tolerability of single and repeated intranasal doses of OP0201. We are currently conducting one exploratory phase 2a clinical trial of OP0201 nasal aerosol in infants and children with acute otitis media. Upon completion of the phase 2a clinical study, we intend to initiate phase 2 and phase 3 studies, with an initial focus on a development program that, if successful, will lead to registration of OP0201 nasal aerosol in North America and key European markets as a product to treat OM and prevent OM in infants and 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 generate clinical data for the OP0201 nasal aerosol 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 device development for our drug-device 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 are developing only one of our two drug candidates, OP0102 and OP0201 nasal aerosol. If we are unable to successfully develop and commercialize this candidate (OP0201 nasal aerosol) or any other drug candidate, 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 and device development), manufacturing, nonclinical studies, 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 one or more drug candidates. As a result, our business is substantially dependent on our ability to successfully complete the development of and obtain regulatory approval for our 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 formulation, manufacturing, clinical, and nonclinical development activities;
- manufacture drug product at commercial scale;
- establish and confirm commercially acceptable stability (shelf-life) of our drug products;
- in-license or acquire other product candidates and advance them through clinical development;
- obtain required regulatory approvals for the development and commercialization of OP0201 nasal aerosol 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 OP0201 nasal aerosol and/or 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 our 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, and, until May 2017, early stage clinical studies of our most advanced product candidate, OP0101 otic foam. In May 2017, we paused the OP0101 otic foam development program and began focusing substantially all of our resources on the advancement of our surfactant program (OP0201 nasal aerosol) for otitis media. Since then, operations related to OP0201 nasal aerosol have included arranging for third party vendors to formulate and manufacture cGMP clinical material as well as preparing and conducting three phase 1 clinical studies and one phase 2a clinical study. Additional phase 2 clinical trial preparation activities are also ongoing. 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 U.S. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the formulation and commercialization of our product candidates.

We will continue to conduct OP0201 nasal aerosol formulation and device development as the product advances through clinical development. We are highly dependent on third parties for OP0201 nasal aerosol formulation and device development as well as manufacturing of drug product. Although we have been successful in manufacturing cGMP batches for phase 1 clinical trials and a phase 2a clinical trial, these have been at a smaller scale. We may not be successful in scaling-up manufacturing for subsequent larger clinical trials.

Reformulation work for our otic foam product to explore adding a second active ingredient (anesthetic) to address immediate relief of ear pain associated with AOE commenced in 2016 but was subsequently put on hold. If the reformulation work is resumed, additional formulation development and clinical studies with the new combination product (antibiotic + anesthetic) will need to be conducted. There is a risk that additional nonclinical and/or clinical safety studies will be required by the U.S. Food and Drug Administration ("FDA") or similar regulatory authorities outside the U.S. and/or that subsequent studies will not match results seen in prior studies with earlier otic foam formulations.

Given the early stage of development for both product candidates, the risk of failure is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate we currently are developing and/or future product candidates, we must ensure that formulation and device (as applicable) development manufacturing, nonclinical trials, and clinical trials to demonstrate the safety and efficacy of our product candidates in humans are conducted. Formulation and device (as applicable) development, manufacturing, nonclinical and clinical trials are all expensive activities, difficult to design and implement, and can take years to complete. The outcomes of formulation and device development, manufacturing, nonclinical and clinical trials are all inherently uncertain. Failure can occur at any time during the development program. 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. For instance, results from nonclinical trials conducted with an earlier formulation of the surfactant product may not be predictive of the results of our OP0201 nasal aerosol clinical studies. 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 ("EMA"), or the Medicines & Healthcare Products Regulatory Agency ("MHRA") the United Kingdom regulatory authority, will approve Clinical Trial Application's for any of our product candidates in the future. There is also no assurance that 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 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 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 or failure in completing formulation development and manufacturing work as a prerequisite to commencing cGMP manufacture of clinical trial material;
- 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;
- 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.

Additionally, because we are developing a drug-device combination product (OP0201 nasal aerosol), we will be subject to greater regulatory scrutiny and technical challenges. Devices such as our metered-dose inhaler are regulated by a separate division within the FDA. Even if our drug compound is shown to be safe and effective, our delivery device must also demonstrate that it can reliably deliver a consistent dose of the drug across repeated uses. This is challenging and is subject to a further layer of regulatory review before our product can be approved. If we are unsuccessful in addressing these technical and regulatory challenges, our prospects could be adversely affected.

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 do not know whether the planned 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;
- seasonality of disease(s) being studied;
- 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. Any occurrences of clinically significant adverse events with our product candidates may harm our business, financial condition and prospects significantly.

OP0201 nasal aerosol is an early-product candidate, and the side effect profile in humans has not been fully established. Currently unknown, drug-related side effects may be identified through ongoing and future OP0201 nasal aerosol clinical studies and, as such, these possible drug-related side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial, or result in potential product liability claims.

Any new formulations of otic foam would be an early-product candidate. The side effect profile of any new formulations of otic foam will need to be established in animals and humans. It may be a product with an unacceptable side effect profile.

Risks Related to Our Financial Position and Need for Additional Capital

We have concluded and disclosed in the footnotes to our unaudited condensed consolidated financial statements, included elsewhere within this Quarterly Report on Form 10-Q, that we do not have sufficient cash to fund our operations through 12 months from the date of issuance of the most recent financial statements.

Our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q have been prepared on a basis that assumes that we will continue as a going concern and does not include any adjustments that may result from the outcome of this uncertainty.

Our ability to continue as a going concern is dependent upon a number of factors, including our ability to obtain the necessary financing to meet our obligations and repay our liabilities arising from obligations that become due in the ordinary course of business. Management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock or the issuance of debt. There can be no guarantee that we will successfully raise all the funding we require. However, substantial doubt about a company’s ability to continue as a going concern is generally viewed unfavorably by current and prospective investors, as well as by analysts and creditors. As a result, it may be more difficult for us to raise the additional financing necessary to continue to operate our business and we may be forced to significantly alter our business strategy, substantially curtail our current operations, or cease operations altogether.

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.

We have sufficient capital to complete the ongoing OP0201 nasal aerosol phase 1 and phase 2a clinical studies but will require additional capital to conduct additional OP0201 nasal aerosol studies and ultimately commercialize OP0201 nasal aerosol if approved. We may also need to raise additional funds to pursue other development activities related to additional product candidates that we may develop. Our funding needs may fluctuate significantly based on a number of factors, such as:

- the scope, progress, results and costs of formulation and device development and manufacture of drug/drug device 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting 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, the trading price of the Company's common stock could decline. At March 31, 2019, the Company had approximately 9.4 million shares of common stock outstanding.

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 U.S. and by other regulatory authorities outside the U.S. prior to commercialization in regions outside of the U.S.. The process of obtaining marketing approvals, both in the U.S. and outside the U.S., 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 U.S.

In order to market and sell our products in the European Union ("EU") and other international jurisdictions outside of the U.S., 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 U.S. generally includes all the risks associated with obtaining FDA approval. In addition to regulatory approval, in many countries outside the U.S., 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 U.S. 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 U.S. 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 may 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 U.S. and other countries that follow the International Conference on Harmonization, 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 healthcare 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 EU 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 EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Legislation regulating the pharmaceutical and healthcare industries 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 U.S. 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, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "PPACA") substantially changed the way healthcare is financed by both governmental and private insurers, significantly impacting the U.S. pharmaceutical industry. The PPACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, and establishes annual fees and taxes on manufacturers of certain branded prescription drugs. Implementation of the PPACA remains ongoing, but there is uncertainty as to how the law's various provisions will ultimately affect the industry and whether all aspects of the law will remain in place.

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.

We expect that additional state and federal healthcare reform measures and regulations will be adopted in the future. Any of these measures and regulations could limit the amounts that federal and state governments will pay for healthcare products and services, result in reduced demand for our product candidates or additional pricing pressures and affect our product development, testing, marketing approvals and post-market activities.

Laws, restrictions, and other regulatory measures are also imposed by healthcare laws and regulations in international jurisdictions. In those jurisdictions we face the same issues as in the U.S. 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 U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the EU, 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, ("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 healthcare 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. 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 our current product candidates, 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. 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.

In OM, there are currently no drug therapies approved for the treatment or prevention of OM in children or adults. We expect that OP0201 nasal aerosol 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 treating OM and preventing recurrent or chronic OM. We may also compete with a medical device that uses a small intranasal balloon inserted into the ET to ventilate the ET in adults with ETD. Surgery to insert tympanostomy tubes may continue to be the preferred treatment for OM in children whereas the intranasal balloon may be the preferred treatment for ETD in adults. Patients may be prescribed concurrent antibiotic therapy for AOM, but these products will not be competitive with, but likely will be used in conjunction with OP0201 nasal aerosol.

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 for treatment of otitis externa, with additional products expected to become available over the coming years, potentially creating pricing pressure. If our otitis externa product candidates (e.g. otic foam) 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 U.S., 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 U.S., 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 U.S. 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 U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payers, in the U.S. 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 $5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $5.0 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 or commercialization of our product candidates. 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 could 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, manufacturing, 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 a sole supplier for our active pharmaceutical ingredients ("API"), and a different sole manufacturer for our OP0201 nasal aerosol product candidate. 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 supplier or our manufacturer. 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.

Formulations and devices used in early studies are not final formulations and devices 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 result in a delay in our clinical trials and commercialization activities.

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 U.S. 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.

We depend on CROs and other contracted third parties to perform nonclinical and clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control.

The nature of outsourcing a substantial portion of our business will require that we rely on CROs and other contractors to assist us with research and development, clinical testing activities, patient enrollment, data collection, and regulatory submissions to the FDA or other regulatory bodies. As a result, our success will depend partially on the success of these third parties in performing their responsibilities. Although we intend to pre-qualify our CROs and other contractors and we believe that the contractors selected will be fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, macro-economic conditions may affect our development partners and vendors, which could adversely affect their ability to timely perform their tasks. If our contractors do not perform their obligations in an adequate and timely manner, the pace of clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed, and our prospects could be adversely affected.

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 EU, the U.S. and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the U.S. and internationally that are related to our novel technologies and product candidates. This patent portfolio includes issued patents and pending patent applications covering pharmaceutical compositions and 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 U.S. 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 U.S. 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 EU, the U.S. 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 U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. 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 U.S. 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 U.S. 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 experience 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 OP0201 surfactant nasal aerosol product 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 are not able to obtain a license, or are 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 non-disclosure 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 U.S. 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 EU 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 our product candidates 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 who understand 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 65.7% of our capital stock as of March 31, 2019. 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, 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 accounting principles generally accepted in the U.S. ("GAAP").

Our financial statements have only been prepared in accordance with GAAP since May 2017. Since that time, we have implemented measures designed to improve our internal controls over financial reporting, including by bringing in additional accounting resources and establishing new accounting and financial reporting procedures to establish an appropriate level of internal controls over financial reporting. If we are unable to successfully maintain 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 Delaware General Corporation Law, 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
10.1	Management Continuity Agreement, date August 7, 2017, between Novus Therapeutics, Inc. and Catherine C. Turkel
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.

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: May 14, 2019	By:	/s/ Gregory J. Flesher
		Gregory J. Flesher **Chief Executive Officer and Director (Principal Executive Officer)**
Date: May 14, 2019	By:	/s/ Jon S. Kuwahara
		Jon S. Kuwahara **Senior Vice President Finance & Administration (Principal Financial and Accounting Officer)**

Exhibit 10.1

NOVUS THERAPEUTICS, INC. MANAGEMENT CONTINUITY AGREEMENT

This Management Continuity Agreement (the **"Agreement")** is effective as of August 7, 2017 (the **"Effective Date")** by and between Catherine C. Turkel **("Employee")** and Nevus Therapeutics. Inc, a Delaware corporation (the **"Company").** This Agreement is intended to provide Employee with certain benefits described herein upon the occurrence of specific events.

RECITALS

A It is expected that the Company may from time to time consider the possibility of realigning its organization.

B It is further expected that another company may from time to time consider the possibility of acquiring the Company or that a change in control may otherwise occur, with or without the approval of the Company's Board of Directors.

C The Board of Directors recognizes that such considerations can be a distraction to Employee and can cause Employee to consider alternative employment opportunities.

D The Board of Directors has determined that it is in the best interests of the Company and its shareholders to assure that the Company will have the continued dedication and objectivity of Employee, notwithstanding the foregoing factors.

E The Company's Board of Directors believes it is in the best interests of the Company and its shareholders to retain Employee and provide incentives to Employee to continue in the service of the Company.

F The Board of Directors further believes that it is imperative to provide Employee with certain benefits upon certain termination of Employee's employment, including in connection with a Change in Control, which benefits are intended to provide Employee with financial security and provide sufficient income and encouragement to Employee to remain with the Company, including and notwithstanding the possibility of a Change in Control.

G To accomplish the foregoing objectives, the Board of Directors has directed the Company, upon execution of this Agreement by Employee, to agree to the terms provided in this Agreement, which Agreement shall supersede any agreement or understanding pertaining to the subject matter herein, including any offer letter between the Company and Employee, as of the Effective Date.

Now therefore, in consideration of the mutual promises, covenants and agreements contained herein, and in consideration of the continuing employment of Employee by the Company, the parties hereto agree as follows:

1. **AT-WILL EMPLOYMENT.**

The Company and Employee acknowledge that Employee's employment is and shall continue to be at-will, as defined under applicable law, and that Employee's employment with the Company may be terminated by either party at any time, with or without Cause or notice. If Employee's employment terminates for any reason, Employee shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement. The rights and duties created by this Agreement are contingent upon Employee's (i) full compliance with any confidentiality, inventions, and non-solicitation agreement between Employee and the Company (an **"Ancillary Agreement"),** and (ii) execution ofa severance and release of claims agreement provided by the Company (the **"Severance Agreement")** within forty-five (45) days following his/her termination of employment (or such lesser period as is then required by the Severance Agreement), and (iii) such Severance Agreement becoming effective and irrevocable in accordance with its term no later than sixty (60) days following termination of employment. The Severance Agreement may not be modified in any way except by a written agreement executed by Employee and an officer of the Company upon direction from the Board of Directors.

2. **TERMINATION BENEFITS.**

(a) Benefits Upon a Change in Control Involuntary Termination.

(i) Treatment of Equity Awards. In the event that Employee is subject to a Change in Control Involuntary Termination, 100% of Employee's unvested Company equity-based awards (including, but not limited to, stock options, restricted stock, restricted stock units, and stock appreciation rights) shall become immediately vested on such termination date and the risk of forfeiture of 100% of Employee's restricted stock, if any, shall lapse on such termination date. Each such equity award shall be exercisable in accordance with the provisions of the award agreement and plan pursuant to which such equity award was granted, including, in the case of stock options, the plan or award agreement provisions regarding any post-termination period of exercisability.•

(ii) Severance. In the event that Employee is subject to a Change in Control Involuntary Termination, Employee shall be entitled to receive severance benefits as follows: (A) a lump sum cash severance payment equal to 1.0 multipli_ed by the sum of (x) the annual base salary which Employee was receiving immediately prior to the Change in Control Involuntary Termination, plus (y) the larger of (1) Employee's annual target bonus or (2) the annual bonus earned by Employee for the year preceding the year of termination; (B) a lump sum cash payment equal to a pro-rata portion of Employee's target annual bonus amount for the year in which the Change in Control Involuntary Termination occurs; and (C) payment by the Company of the full cost of the health insurance benefits provided to Employee and Employee's spouse and dependents, as applicable, immediately prior to the Change in Control pursuant to the terms of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended **("COBRA")** or other applicable law through the earlier of the end of the 12-month period following the Change in Control Involuntary Termination date or the date upon which Employee is no longer eligible for such COBRA or other benefits under applicable law, provided that if the Company's paying for health insurance benefits violates nondiscrimination laws, the payments will cease. The benefits to be provided under clauses (a)(i) and (a)(ii) shall be paid or commence to be paid on the first payroll date following the date that the Severance Agreement becomes effective and irrevocable (provided that if the forty-five (45) day period to execute the Severance Agreement ends in a calendar year subsequent to the year in which Employee was terminated, payment will not begin before the first business day of that subsequent year). Notwithstanding the foregoing, in the event the Board of Directors concludes in its reasonable judgment that the provision of subsidized COBRA benefits to Employee is likely to cause the Company to become subject to an excise tax under applicable law, the Company shall pay Employee a monthly amount in cash equal to the amount of the COBRA subsidy during the period the Company is obligated to provide subsidized COBRA benefits to Employee.

(b) Benefits Upon an Other Involuntary Termination.

(i) Severance. In the event that Employee is subject to an Other Involuntary Termination, Employee shall be entitled to receive severance benefits as follows: (A) continued payment of Employee's base salary that Employee was receiving immediately prior to the Other Involuntary Termination for 9-months after the date of the termination (for purposes of this Section 2(b)(i), the **"Severance Period"),** which payments shall be paid during the Severance Period in accordance with the Company's standard payroll practices; and (B) payment by the Company of the full cost of the health insurance benefits provided to Employee and Employee's spouse and dependents, as applicable, immediately prior to the Other Involuntary Termination pursuant to the terms of COBRA or other applicable law through the earlier of the end of the Severance Period or the date upon which Employee is no longer eligible for such COBRA or other benefits under applicable law, provided that if the Company's paying for health insurance benefits violates nondiscrimination laws, the payments will cease. The benefits to be provided under Section 2(b)(i) shall be paid or commence to be paid on the first payroll date following the date that the Severance Agreement becomes effective and irrevocable (provided that if the forty-five (45) day period to execute the Severance Agreement ends in a calendar year subsequent to the year in which Employee was terminated, payment will not begin before the first business day of that subsequent year), subject to Employee's compliance with any Ancillary Agreement and execution, release, and non revocation of the Severance Agreement as set forth in Section I. Notwithstanding the foregoing, in the event the Board of Directors concludes in its reasonable judgment that the provision of subsidized COBRA benefits to Employee is likely to cause the Company to become subject to an excise tax under applicable law, the Company shall pay Employee a monthly amount in cash equal to the amount of the COBRA subsidy during the period the Company is obligated to provide subsidized COBRA benefits to Employee.

(c) Termination for Cause or Voluntary Resignation. If Employee's employment is terminated for Cause at any time, if Employee voluntarily resigns from the Company under circumstances which do not constitute a Change in Control Involuntary Termination or an Other Involuntary Termination, or if Employee's employment terminates due to Employee's death or disability, then Employee shall not be entitled to receive payment of any severance benefits or equity award acceleration. Nevertheless, Employee shall receive payment(s) for all salary, bonuses and unpaid vacation accrued as of the date of Employee's termination of employment.

3. **DEFINITION OF TERMS.** The following terms referred to in this Agreement shall have the following meanings:

(a) Cause. **"Cause"** means: (i) Employee's conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude or any felony; or (ii) a good faith finding by the Company that Employee has (x) engaged in dishonesty, willful misconduct or gross negligence in connection with the performance of your duties or services te the Company, (y) breached an Ancillary Agreement, or (z) violated Company policies or procedures in a manner that has materially injured, or is reasonably likely to materially injure, the Company's business or reputation.

(b) Change in Control. **"Change in Control"** means:

(i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or I4(d)(2) of the Securities Exchange Act of 1934, as amended (the **"Exchange Act")) (a "Person")** of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule I3d-3 promulgated under the Exchange Act) 50% or more of the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the **"Outstanding Company Voting Securities");** provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (x) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), or (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(ii) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company (a **"Business Combination"),** unless, immediately following such Business Combination all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Outstanding Company Voting Securities immediately prior to such Business Combination: provided that, where required to avoid additional taxation under Section 409A of the Internal Revenue Code of 1986, as amended (the **"Code"),** the event that occurs must also be a "change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portion of the assets of a corporation" as defined in Treasury Regulation Section 1.409A-3(i)(5).

(c) Change in Control Involuntary Termination. **"Change in Control Involuntary Termination"** shall mean: (i) any termination by the Company other than for Cause (not including a termination as a result of Employee's death or disability), or (ii) Employee's voluntary termination for Good Reason, in each case in connection with, or within the period ending twelve (12) months following the effective date of a Change in Control.

(d) Good Reason. **"Good Reason"** means: (i) a material adverse change in Employee's duties, responsibilities, title or reporting relationship, (ii) a material reduction in Employee's annualized base salary without your prior consent (other than in connection with, and in an amount substantially proportionate to, reductions made by the Company to the annualized base salaries of its other senior executives), or (iii) the relocation of Employee's principal business location following a Change in Control, such that Employee's daily commute is increased by at least 50 miles. To terminate Employee's employment for Good Reason, Employee must (x) provide notice to the Company of the event giving rise to the Good Reason within ninety (90) days after such event occurs, (y) provide the Company with at least thirty (30) days to cure, and (z) if not cured, resign for Good Reason within thirty (30) days following expiration of the cure period.

(e) Other Involuntary Termination. **"Other Involuntary Termination"** shall mean (i) any termination by the Company other than for Cause (not including a termination as a result of Employee's death or disability), or (ii) Employee's voluntary termination for Good Reason, in each case, excluding a Change in Control Involuntary Termination.

4. LIMITATION AND CONDITIONS ON PAYMENTS.

In the event that the severance and other benefits provided to Employee under this Agreement and any other agreement (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section, would be subject to the excise tax imposed by Section 4999 of the Code, then Employee's severance benefits under Sections 2(a) and 2(b) shall be payable either:

(a) in full; or

(b) as to such lesser amount which would result in no portion of such severance benefits being subject to excise tax under Section 4999 of the Code;

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Employee on an after-tax basis, of the greatest amount of severance benefits under Section 2(a) and 2(b), notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. The reduction of payments and benefits hereunder, if

applicable, shall be made by reducing, first, cash severance pay that is exempt from Section 409A of the Code; second, any other cash severance pay; third, any other payments or benefits to be paid in cash hereunder in the order in which such payment or benefit would be paid or provided (beginning with such payment or benefit that would be made last in time and continuing, to the extent necessary, through to such payment or benefit that would be made first in time); fourth, reducing any benefit to be provided in kind hereunder in a similar order, except for equity-based awards; fifth, any restricted stock, restricted stock units or similar awards, to be reduced in a similar order; and lastly, sixth, any stock options, stock appreciation right or similar awards, to be reduced in a similar order. Unless the Company and Employee otherwise agree in writing, any determination required under this Section 4 shall be made in writing by a qualified independent certified public accounting or law firm selected by the Company and approved by Employee, which such approval shall not be unreasonably withheld (the **"Independent Tax Professional").** Employee shall not be deemed to have unreasonably withheld approval if Employee does not consent to an Independent Tax Professional selected by the Company that has provided any services to the Company or any successor corporation within the preceding five (5) year period. The Independent Tax Professional shall provide its determinations and any supporting calculations both to the Company and Employee in writing setting forth in reasonable detail the basis of the Independent Tax Professional's determinations, which shall be subject to approval by Employee, which such approval shall not be unreasonably withheld. Such determination shall be conclusive and binding upon Employee and the Company for all purposes. For purposes of making the calculations required by this Section 4, the Independent Tax Professional may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Section 280G and 4999 of the Code. The Company and Employee shall furnish to the Independent Tax Professional such information and documents as the Independent Tax Professional may reasonably request in order to make a determination under this Section. The Company shall bear all costs the Independent Tax Professional may reasonably incur in connection with any calculations contemplated by this Section 4. If, after the payment of severance benefits has been made to Employee, it is established that the payments made to, or provided for the benefit of Employee, exceed the limitations provided in Section 4(b) (an **"Excess Payment")** or are less than such limitations (an **"Underpayment"),** as the case may be, then the following shall apply:
(x) if it is determined that an Excess Payment has been made, Employee shall repay the Excess Payment within 20 days following the determination of such Excess Payment; and (y) if it is determined that an Underpayment has occurred, the Company shall pay an amount equal to the Underpayment to Employee on the later of (A) 20 days after such determination or resolution and (B) the time period such payment would otherwise have been paid or provided to Employee absent the application of Section 4(b).

5. **SECTION 409A.** Notwithstanding any provision of this Agreement to the contrary, if, at the time of Employee's termination of employment with the Company, Employee is a "specified employee" (as defined in Section 409A of the Code) and the deferral of the commencement of any severance payments or benefits otherwise payable pursuant to this Agreement as a result of such termination of employment is necessary in order to prevent any accelerated income recognition or additional tax under Section 409A of the Code, then the Company will not commence any payment of any such severance payments or benefits otherwise required hereunder (but without any reduction in such payments or benefits ultimately paid or provided to Employee) that (a) will not and may not under any circumstances, regardless of

when such termination occurs, be paid in full by March 15 of the year following Employee's termination of employment, and (b) are in excess of the lesser of (i) two (2) times Employee's then annual compensation or (ii) two (2) times the limit on compensation then set forth in Section 401(a)(l 7) of the Code and will not be paid by the end of the second calendar year following the year in which the termination occurs, *until* the first payroll date that occurs after the date that is six (6) months following Employee's "separation of service" with the Company (as defined under Code Section 409A). If any payments are delayed due to such requirements, such amounts will be paid in a lump sum to Employee on the earliest of (x) Employee's death following the date of Employee's termination of employment with the Company or (y) the first payroll date that occurs after the date that is six (6) months following Employee's "separation of service" with the Company. For these purposes, each severance payment or benefit is designated as a separate payment or benefit for purposes of Treasury Regulation Section 1.409A-2(b) and will not collectively be treated as a single payment or benefit. This paragraph is intended to comply with the requirements of Section 409A of the Code so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A of the Code and any ambiguities herein will be interpreted to so comply.
Employee and the Company agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Employee under Section 409A of the Code. Notwithstanding anything to the contrary contained herein, to the extent that any amendment to this Agreement with respect to the payment of any severance payments or benefits would constitute under Code Section 409A a delay in a payment or a change in the form of payment, then such amendment must be done in a manner that complies with Code Section 409A(a)(4)(C).

6. **CONFLICTS.** Employee represents that Employee's performance of all the terms of this Agreement will not breach any other agreement to which Employee is a party. Employee has not, and will not during the term of this Agreement, enter into any oral or written agreement in conflict with any of the provisions of this Agreement. Employee further represents that Employee is entering into or has entered into an employment relationship with the Company of Employee's own free will.

7. **SUCCESSORS.** Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. The terms of this Agreement and all of Employee's rights hereunder and thereunder shall inure to the benefit of, and be enforceable by, Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

8. **NOTICE.** Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to Employee shall be addressed to Employee at the home address which Employee most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of the Company's Legal Department.

9. MISCELLANEOUS PROVISIONS.

(a) No Duty to Mitigate. Employee shall not be required to mitigate the amount of any payment contemplated by this Agreement (whether by seeking new employment or in any other manner), nor shall any such payment be reduced by any earnings that Employee may receive from any other source.

(b) Waiver. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Employee and by an authorized officer of the Company (other than Employee). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Whole Agreement. No agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement supersedes the severance and change of control terms of that certain Executive Employment Agreement between the Executive and Otic Pharma Inc., dated as of • November 10, 2015, and any other agreement with the Company and its subsidiaries concerning similar subject matter dated prior to the date hereof; by execution of this Agreement, both parties agree that any relevant provisions of such predecessor agreement(s) shall be deemed null and void.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California without reference to conflict of laws provisions.

(e) Severability. If any term or provision of this Agreement or the application thereof to any circumstance shall, in any jurisdiction and to any extent, be invalid or unenforceable, such term or provision shall be ineffective as to such jurisdiction to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining terms and provisions of this Agreement or the application of such terms and provisions to circumstances other than those as to which it is held invalid or unenforceable, and a suitable and equitable term or provision shall be substituted therefor to carry out, insofar as may be valid and enforceable, the intent and purpose of the invalid or unenforceable term or provision.

(f) Legal Fees and Expenses. The parties shall each bear their own expenses, legal fees and other fees incurred in connection with entering into this Agreement.

(g) No Assignment of Benefits. The rights of any person to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation oflaw, including (without limitation) bankruptcy, garnishment, attachment or other creditor's process, and any action in violation of this Section 9(g) shall be void.

(h) Employment Taxes. All payments made pursuant to this Agreement will be subject to withholding of applicable income and employment taxes.

(i) Assignment by Company. The Company may assign its rights under this Agreement to an affiliate, and an affiliate may assign its rights under this Agreement to another affiliate of the Company or to the Company. In the case of any such assignment, the term **"Company"** when used in a section of this Agreement shall mean the corporation that actually employs Employee. Notwithstanding the foregoing, neither the Company (or any successor thereto) nor Employee may assign its obligations under this Agreement.

G) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS]

The parties have executed this Management Continuity Agreement on the date first written above.

NOVUS THERAPEUTICS, INC.

By:

Name: !J\..4..-

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President + CEO

Title:

8/5/2017 **EMPLOYEE** (. J

Catherine C. Turkel

Address: f'1 $ iJf'fu._, Ci1

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Irvine, CA 92612

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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: May 14, 2019

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: May 14, 2019

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 March 31, 2019 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 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: May 14, 2019

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 March 31, 2019 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: May 14, 2019

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