

**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 **June 30, 2020**

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)

1990 MacArthur Blvd., Suite 550
Irvine, California
(Address of principal executive offices)

20-1000967
(I.R.S. Employer
Identification No.)

92612
(Zip Code)

(949) 238-8090

Registrant's telephone number, including area code

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 August 11, 2020, there were 19,384,562 shares of the Registrant's common stock outstanding.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains “forward-looking statements” as defined by the Private Securities Litigation Reform Act of 1995, which statements 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 words such as “believes,” “anticipates,” “plans,” “expects,” “estimates,” “intends,” “predicts,” “projects,” “targets,” “could,” “may,” and similar expressions, constitute forward-looking statements, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding:

- the impact of the COVID-19 pandemic on our operations, including our ability to access capital markets;
- the anticipated expenses associated with a workforce reduction that we effected in June 2020;
- our board of directors’ review of strategic alternatives;
- the Company’s ability to regain compliance with the Nasdaq listing criteria in a timely manner;
- expectations regarding the timing for the commencement and completion of product development or clinical trials for the Company’s product candidates;
- the timing, costs, conduct and outcome of preclinical studies and clinical trials;
- meeting future clinical and regulatory milestones, such as New Drug Application (“NDA”) submissions;
- the risk that clinical trials of the Company’s product candidates may not be successful in establishing safety and tolerability or efficacy;
- the Company’s plans and timing with respect to seeking regulatory approvals and uncertainties regarding the regulatory process;
- the anticipated treatment of data by the U.S. Food and Drug Administration (“FDA”), the European Medicines Agency (“EMA”) or other regulatory authorities of the Company’s product candidates;
- the rate and degree of market acceptance and clinical utility of the Company’s product candidates;
- 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 product candidates with significant commercial potential;
- the availability of funds and resources to pursue the Company’s research and development projects, including preclinical studies and clinical trials of its product candidates, and manufacturing activities.
- the Company’s estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the Company’s ability to continue as a going concern;
- developments relating to the Company’s competitors and industry;
- the impact of government laws and regulations; and
- the duration over which the Company’s cash balances will fund its operations.

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 on a timely basis, or at all; 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 FDA or equivalent foreign regulatory agencies and, if the Company is able to obtain such approval for an investigational product, whether it will be successfully distributed and marketed; and the severity, magnitude and duration of the COVID-19 pandemic, including economic and other impacts of the pandemic and of and actions taken in response to it by governments, businesses, and individuals. 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 Part II, Item 1A, *Risk Factors in this Quarterly Report on Form 10-Q*.

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 JUNE 30, 2020

Table of Contents

	<u>Page</u>
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	5
Condensed Consolidated Balance Sheets as of June 30, 2020 (Unaudited) and December 31, 2019	5
Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2020 and 2019 (Unaudited)	6
Condensed Consolidated Statements of Stockholders' Equity for the Three and Six Months Ended June 30, 2020 and 2019 (Unaudited)	7
Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2020 and 2019 (Unaudited)	8
Notes to Condensed Consolidated Financial Statements	9
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	21
Item 3. Quantitative and Qualitative Disclosures About Market Risk	29
Item 4. Controls and Procedures	29
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	31
Item 1A. Risk Factors	31
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	59
Item 3. Defaults Upon Senior Securities	59
Item 4. Mine Safety Disclosures	59
Item 5. Other Information	59
Item 6. Exhibits	59
Exhibit Index	60
Signatures	61

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2020 (Unaudited)	December 31, 2019 (Note 2)
ASSETS		
Current assets:		
Cash	\$ 8,764	\$ 8,791
Prepaid expenses and other current assets	997	1,180
Total current assets	9,761	9,971
Property and equipment, net	1	5
Operating lease asset, net	228	316
Other assets	511	639
Total assets	<u>\$ 10,501</u>	<u>\$ 10,931</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 150	\$ 329
Current operating lease liability	188	180
Accrued severance	490	—
Accrued expenses and other liabilities	269	813
Total current liabilities	1,097	1,322
Non-current operating lease liability	48	144
Total liabilities	1,145	1,466
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized at June 30, 2020 and December 31, 2019; 511 and 0 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at June 30, 2020 and December 31, 2019; 19,379,562 and 12,967,338 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	19	13
Additional paid-in capital	77,682	67,034
Accumulated deficit	(68,345)	(57,582)
Total stockholders' equity	9,356	9,465
Total liabilities and stockholders' equity	<u>\$ 10,501</u>	<u>\$ 10,931</u>

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 June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	\$ 832	\$ 2,297	\$ 2,480	\$ 5,286
General and administrative	1,269	1,792	2,999	3,678
Restructuring expense	490	—	490	—
Total operating expenses	<u>2,591</u>	<u>4,089</u>	<u>5,969</u>	<u>8,964</u>
Loss from operations	(2,591)	(4,089)	(5,969)	(8,964)
Other income (expense), net	5	(4)	35	(10)
Warrant inducement expense	—	—	(4,829)	—
Net loss and comprehensive loss	<u>\$ (2,586)</u>	<u>\$ (4,093)</u>	<u>\$ (10,763)</u>	<u>\$ (8,974)</u>
Net loss per share, basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.35)</u>	<u>\$ (0.63)</u>	<u>\$ (0.85)</u>
Weighted-average common shares outstanding, basic and diluted	<u>16,981,540</u>	<u>11,751,110</u>	<u>17,124,331</u>	<u>10,595,511</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit
	Shares	Amount	Shares	Amount		
Balance as of December 31, 2019	—	\$ —	12,967,338	\$ 13	\$ 67,034	\$ (57,582)
Issuance of common stock in connection with exercise of warrants, net of issuance costs	—	—	6,898,224	7	5,184	—
Issuance of common stock in connection with conversion of preferred stock	(3,285)	—	3,285,000	3	(3)	—
Issuance of common stock in connection with vesting of restricted stock units	—	—	25,000	—	—	—
Cancellation of common stock in connection with exchange for preferred stock	3,796	—	(3,796,000)	(4)	4	—
Warrant inducement expense	—	—	—	—	4,829	—
Stock-based compensation	—	—	—	—	634	—
Net loss and other comprehensive loss	—	—	—	—	—	(10,763)
Balance as of June 30, 2020	511	\$ —	19,379,562	\$ 19	\$ 77,682	\$ (68,345)
Balance as of March 31, 2020	3,796	\$ —	16,069,562	\$ 16	\$ 77,488	\$ (65,759)
Issuance of common stock in connection with conversion of preferred stock	(3,285)	—	3,285,000	3	(3)	—
Issuance of common stock in connection with vesting of restricted stock units	—	—	25,000	—	—	—
Stock-based compensation	—	—	—	—	197	—
Net loss and other comprehensive loss	—	—	—	—	—	(2,586)
Balance as of June 30, 2020	511	\$ —	19,379,562	\$ 19	\$ 77,682	\$ (68,345)
Balance as of December 31, 2018	—	\$ —	9,422,143	\$ 9	\$ 56,054	\$ (41,571)
Issuance of common stock at-the-market, net of issuance costs	—	—	25,218	—	107	—
Issuance of common stock and warrants in registered direct offering, net of issuance costs	—	—	3,449,112	4	9,565	—
Issuance of common stock in connection with exercise of options	—	—	78,450	—	—	—
Stock-based compensation	—	—	—	—	838	—
Net loss and other comprehensive loss	—	—	—	—	—	(8,974)
Balance as of June 30, 2019	—	\$ —	12,974,923	\$ 13	\$ 66,564	\$ (50,545)
Balance as of March 31, 2019	—	\$ —	9,447,361	\$ 9	\$ 56,372	\$ (46,452)
Issuance of common stock and warrants in registered direct offering, net of issuance costs	—	—	3,449,112	4	9,565	—
Issuance of common stock in connection with exercise of options	—	—	78,450	—	—	—
Stock-based compensation	—	—	—	—	627	—
Net loss and other comprehensive loss	—	—	—	—	—	(4,093)
Balance as of June 30, 2019	—	\$ —	12,974,923	\$ 13	\$ 66,564	\$ (50,545)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	For the Six Months Ended June 30,	
	2020	2019
Operating activities		
Net loss	\$ (10,763)	\$ (8,974)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4	4
Amortization of operating lease asset	88	86
Warrant inducement expense	4,829	—
Stock-based compensation	634	838
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	311	(60)
Accounts payable and accrued expenses	(233)	(759)
Operating lease liability	(88)	(80)
Net cash used in operating activities	(5,218)	(8,945)
Financing activities		
Proceeds from issuances of common stock, net	—	9,676
Proceeds from exercise of warrants, net	5,191	—
Net cash provided by financing activities	5,191	9,676
Net change in cash	(27)	731
Cash at beginning of period	8,791	12,972
Cash at end of period	\$ 8,764	\$ 13,703

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1. Description of Business

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

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) and Article 8 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, 2019 included in the Annual Report on Form 10-K filed by the Company with the SEC on March 16, 2020. The results of operations and comprehensive loss for the three and six months ended June 30, 2020 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. The activities of the Company’s foreign subsidiary are not significant to the condensed consolidated financial statements.

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 \$2.6 million and \$10.8 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2020, the Company had cash of \$8.8 million, working capital of \$8.7 million and an accumulated deficit of \$68.3 million. Due to continuing operational 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. The Company’s ability to raise additional capital in the equity and debt markets is dependent on a number of factors, including, but not limited to, the market demand for the Company’s common stock, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company. 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.

Adequate additional funding may not be available to us on acceptable terms on a timely basis, or at all. During fiscal year 2019 and in the first six months of 2020, the Company has implemented, and will continue to implement, certain cost cutting measures to reduce its cash flow requirements, including a reduction in force, which was announced in June 2020. Consistent with the actions the Company has taken in the past, it will execute the appropriate steps to enable the continued operation of the business and preservation of the value of its assets, 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 as it seeks strategic alternatives.

On August 8, 2019, the Company received written notice (the "Notification Letter") from The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities maintain a minimum closing bid price of \$1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company's common stock for the 30 consecutive business days prior to the date of the Notification Letter, the Company did not meet the minimum closing bid price requirement.

The Notification Letter stated that the Company had 180 calendar days, or until February 4, 2020, to regain compliance with Nasdaq Listing Rule 5550(a)(2).

On February 6, 2020, the Company received written notice that Nasdaq determined that it is eligible for an additional 180-day extension (the "Extension Letter"), or until August 3, 2020, to regain compliance with the minimum bid price requirement. The Extension Letter does not impact the Company's listing on the Nasdaq Capital Market at this time. To regain compliance, the closing bid price of the Company's common stock must be at least \$1.00 per share for a minimum of 10 consecutive business days at any time prior to August 3, 2020.

On April 21, 2020, the Company received an additional notice from Nasdaq (the "Tolling Notice"), which stated that, due to current market conditions, Nasdaq has determined to toll the compliance period for the minimum bid price requirement through June 30, 2020. As a result, the new date by which the Company has to regain compliance with the minimum bid price requirement is October 19, 2020.

The Company intends to monitor the closing bid price of its common stock and consider its available options to resolve its noncompliance with the minimum bid price requirement.

On May 12, 2020, the Company's stockholders approved and adopted an amendment to the Company's Restated Certificate of Incorporation to effect a reverse stock split of the Company's common stock at a ratio ranging from 1 share-for-10 shares up to a ratio of 1 share-for-30 shares, which ratio will be selected by the Company's Board of Directors and set forth in a public announcement. Management may effect the reverse stock split at any time prior to December 31, 2020. If the Company's stock price does not meet or exceed \$1.00 per share prior to the compliance deadline, management expects to effect the reverse stock split in order to regain compliance.

There can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or that the Company will otherwise be in compliance with other Nasdaq listing criteria. If the Company fails to regain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the Nasdaq Capital Market in the future and Nasdaq determines to delist its common stock, the delisting could adversely affect the market price and liquidity of the Company's common stock and reduce its ability to raise additional capital.

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

At the time of issuance of the condensed consolidated financial statements for the period ended June 30, 2020, 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 filing of this quarterly report on Form 10-Q. 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 condensed consolidated 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 consolidated 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 condensed consolidated financial statements relate to stock-based transactions, accruals for liabilities, operating lease liability, 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 at June 30, 2020 and December 31, 2019.

Concentration of Credit Risk and Other Risks and Uncertainties

As of June 30, 2020 and December 31, 2019, all of the Company's long-lived assets were located in the United States.

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 the Company's products will receive any of these required approvals. The denial or delay of such approvals may impact the Company's business in the future. In addition, after approval by the FDA, there is still an ongoing risk of adverse events that did not appear during the product approval process.

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.

Our facilities and equipment, including those of our suppliers and vendors, may be affected by natural or man-made disasters. Our administrative office is based in Irvine, California and we manage all our research and development activities through third parties that are located throughout the world. We have taken precautions to safeguard our facilities, equipment and systems, including insurance, health and safety protocols, and off-site storage of computer data. However, our facilities and systems, as well as those of our third-party suppliers and vendors, may be vulnerable to earthquakes, fire, storm, health emergencies, including the ongoing COVID-19 pandemic, power loss, telecommunications failures, physical and software break-ins, software viruses and similar events which could cause substantial delays in our operations, damage or destroy our equipment or inventory, and cause us to incur additional expenses and delay research and development activities. In addition, the insurance coverage we maintain may not be adequate to cover our losses in any circumstance and may not continue to be available to use on acceptable terms, or at all.

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 the development of products for disorders of the ear, nose, and throat.

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 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, as well as reasonable shutdown costs. 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 June 30, 2020.

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 June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
	(In thousands, except share and per share data)			
Net loss and comprehensive loss used in the calculation of basic and diluted loss per share	\$ (2,586)	\$ (4,093)	\$ (10,763)	\$
Net loss per share, basic and diluted	\$ (0.15)	\$ (0.35)	\$ (0.63)	\$
Weighted-average number of common shares outstanding, basic and diluted	16,981,540	11,751,110	17,124,331	10,5

The computation of diluted earnings per share excludes stock options, warrants, and restricted stock units that are anti-dilutive. As of June 30, 2020 and 2019, common share equivalents of 9,481,958 shares and 8,233,947 shares were anti-dilutive, respectively.

Stock-based Compensation

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 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, it determined the expected life assumption using the simplified method for options granted to employees, which is an average of the options ordinary vesting period and the contractual term for 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.

Restricted Stock Units ("RSU") and Performance-Based Restricted Stock Units ("PRSU") are measured and recognized based on the quoted market price of our common stock on the date of grant.

The Company's 2014 Stock Incentive Plan (the "2014 Plan") and 2014 Employee Stock Purchase Plan (the "ESPP" and, together with the 2014 Plan, the "Plans") each provide for an annual increase in shares available for grant, beginning with the fiscal year ending December 31, 2019 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2024.

In March 2020, the board of directors approved an increase of 518,693 shares issuable under the 2014 Plan and 129,673 shares issuable under the ESPP. The number of shares reserved for issuance under the 2014 Plan and ESPP were 401,648 and 433,394 shares, respectively, as of June 30, 2020.

Recently Adopted Accounting Pronouncements

No 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 current assets consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Prepaid insurance	\$ 471	\$ 734
Prepaid clinical	217	102
Prepaid other	64	45
Insurance receivable	162	245
Other current assets	83	54
Total prepaid expenses and other current assets	<u>\$ 997</u>	<u>\$ 1,180</u>

Note 4. Accrued Expenses and Other Liabilities

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

	June 30, 2020	December 31, 2019
Accrued compensation and related expenses	\$ 8	\$ 40
Accrued clinical	32	437
Accrued professional services	105	130
Accrued vacation	115	199
Accrued other	9	7
Total accrued expenses and other liabilities	<u>\$ 269</u>	<u>\$ 813</u>

Note 5. Commitments and Contingencies

Operating Leases

The Company leases office space under a single operating lease. Total rental expense for the operating lease in the accompanying condensed consolidated statements of operations and comprehensive loss was \$47,000 for the three months ended June 30, 2020 and 2019, and \$93,000 and \$95,000 for the six months ended June 30, 2020 and 2019, respectively.

The Company has an operating lease for 5,197 of office space in Irvine, California, that expires on September 30, 2021, as amended.

The Company determines if a contract contains a lease at inception. Our office lease has a remaining term of 1.25 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 as 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's judgment.

Our lease contains 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.

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

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:

	<u>Six Months Ended June 30, 2020</u>
Operating lease cost ^(a)	\$ 98
(a) Includes variable operating lease expenses, which are immaterial	

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

	<u>Six Months Ended June 30, 2020</u>
Supplemental Cash Flows Information	
Cash paid for amounts included in the measurement of lease liability:	
Operating cash flows from operating lease	\$ 93
Remaining lease term	
Operating lease	1.25 years
Discount rate	
Operating lease	3.25%

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

Years ending

2020 (remainder of)	\$ 95
2021	146
Total minimum lease payments	241
Less imputed interest	(5)
Present value of lease liabilities	236
Less current portion	(188)
	<u>\$ 48</u>

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 its 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 has not yet generated sales as of June 30, 2020; 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 the Company 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 related 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 for OP0201 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 United States, 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 six months ended June 30, 2020.

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, the legal predecessor of the Company, completed the initial public offering of its common stock (the "IPO"). On July 25, 2017, a purported stockholder of Tokai filed a lawsuit in the U.S. District Court for the District of Massachusetts, entitled *Peter B. Angelos v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-11365-MLW. The lawsuit was 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 lawsuit alleges that Tokai made false and misleading statements and omissions about its clinical trials for galeterone, in violation of the Securities Act of 1933 and the Securities Exchange Act of 1934. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees.

On September 7, 2018, plaintiff filed an amended complaint. Defendants moved to dismiss the amended complaint on October 15, 2018. Plaintiff opposed defendants' motion on November 19, 2018, defendants filed a reply in support of their motion on December 17, 2018, and plaintiff filed a sur-reply in support of his opposition on January 8, 2019. On February 18, 2020, the court held a hearing on defendants' motion to dismiss. The court also ordered the parties to confer and notify it by March 10, 2020, if they reached an agreement to settle the case. On March 10, 2020, pursuant to the court's order, the parties advised the court they did not agree on a settlement. On July 15, 2020, Plaintiff filed a Notice of Supplemental Authority, and on July 21, 2020, defendants filed a response.

The Company intends to vigorously defend against these claims. Given the uncertainty of litigation, the preliminary stage of this case, 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 this action, and therefore it cannot estimate the reasonably possible loss or range of loss that may result from this action.

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 June 30, 2020.

Note 6. Stockholders' Equity

Equity Distribution Agreement

On July 23, 2018, the Company filed a prospectus and 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. As of December 31, 2019 and June 30, 2020, 25,218 shares have been sold under the 2018 Prospectus for gross proceeds of approximately \$110,000.

2019 Equity Offering

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 (the "Series A Warrants") and Series B warrants to purchase up to 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"). The Series B Warrants become exercisable only upon the exercise of the Series A Warrants. In addition, the Company agreed to issue to the placement agent warrants to purchase up to 172,456 shares of common stock representing 5.0% of the aggregate number of shares of common stock sold in this offering. The placement agent warrants have substantially the same terms as the Series A Warrants issued to the investors in the concurrent private placement, except that the placement agent warrants have an exercise price equal to \$3.87 or 125% of the offering price per share and will expire on April 30, 2024. The registered direct offering and the concurrent private placement are referred to collectively herein as the "2019 Equity Offering."

All the warrants issued in connection with the 2019 Equity Offering contained put options that allow the holders of the warrants the right to receive, for each warrant share that would have been issuable upon an exercise immediately prior to the occurrence of an effective change in control event defined as a fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock for which this warrant is exercisable immediately prior to such fundamental transaction. The Company evaluated the embedded put option contained in the warrants under the guidance of Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging*, and concluded that the requirements for contingent exercise provisions as well as the settlement provision for scope exception in ASC 815-10-15-74 has been met. Accordingly, the put options contained in the warrants were not bi-furcated and accounted for as freestanding derivative instruments.

Warrant Exercise Transaction

On January 10, 2020 and January 15, 2020, the Company entered into warrant exercise agreements (the "Exercise Agreements") with the holders (the "Holders") of its Series A Warrants and Series B Warrants (collectively, the "Warrants"), issued in the 2019 Equity Offering, pursuant to which the Holders agreed to exercise in cash their Warrants to purchase an aggregate of 6,898,224 shares of the Company's common stock at a reduced exercise price of \$0.715 per share, plus an additional \$0.125 per share for the issuance of the private placement warrants for gross proceeds (before placement agent fees and expenses) to the Company of approximately \$5.8 million (the "Exercise Transaction").

Under the Exercise Agreements, the Company also agreed to issue to the Holders new warrants to purchase up to 6,898,224 shares of the Company's common stock at an exercise price of \$0.72 per share, with an exercise period of five and a half years (the "Private Placement Warrants"). The Private Placement Warrants transaction subsequently closed and the Private Placement Warrants were issued on January 14, 2020 with respect to the Warrants exercised on January 10, 2020 and on or about January 17, 2020, with respect to the Warrants exercised on January 15, 2020. In addition, the Company agreed to issue to the placement agent warrants to purchase up to 344,911 shares of common stock, representing 5.0% of the aggregate number of shares of common stock issued in the Exercise Transaction. The placement agent warrants have substantially the same terms as the Private Placement Warrants issued to the Holders, except that the placement agent warrants have an exercise price equal to \$1.05. A warrant inducement expense of \$4.8 million was recorded which was determined using the Black-Scholes option pricing model and was calculated as the difference between the fair value of the Warrants prior to, and immediately after, the reduction in the exercise price on the date of repricing in addition to the fair value of the Private Placement Warrants issued.

As of June 30, 2020, a total of 7,415,591 warrants were available for exercise. The shares of common stock underlying the registered direct placement agent warrants are registered for offer and sale under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to the Company’s effective registration statement on Form S-1 (File No. 333-232011). The shares of common stock underlying the Private Placement Warrants and related placement agent warrants are registered for offer and sale under the Securities Act pursuant to the Company’s effective registration statement on Form S-1 (File No. 333-237379).

The following table shows the warrant activity:

	Rollforward of Warrant Activity					Total
	Registered direct warrants, Series A	Registered direct warrants, Series B	Registered direct warrants, placement agent	Private placement warrants	Private placement warrants, placement agent	
Balance as of December 31, 2019	3,449,112	3,449,112	172,456	—	—	7,070,
Issued	—	—	—	6,898,224	344,911	7,243,
Exercised	(3,449,112)	(3,449,112)	—	—	—	(6,898,
Cancelled/Expired	—	—	—	—	—	—
Balance as of June 30, 2020	—	—	172,456	6,898,224	344,911	7,415,

Common Stock Exchange Agreement

On February 13, 2020, the Company entered into an exchange agreement (the “Exchange Agreement”) with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P. and Biotechnology Value Trading Fund OS, L.P. (the “Exchanging Stockholders”), pursuant to which the Exchanging Stockholders exchanged (the “Exchange”) 3,796,000 shares of the Company’s common stock for 3,796 shares of newly designated Series X Convertible Preferred Stock (the “Series X Preferred Stock”). The Company agreed to reimburse the Exchanging Stockholders for their expenses in connection with the Exchange up to a total of \$25,000, which was recorded as operating expense in the Company’s condensed consolidated statements of operations and comprehensive loss. The Exchange was completed on February 19, 2020.

On February 13, 2020, in connection with the Exchange, the Company filed a Certificate of Designation setting forth the preferences, rights and limitations of the Series X Preferred Stock with the Secretary of State of the State of Delaware. The number of shares so designated shall be 10,000 and Series X Preferred Stock shall have a par value of \$0.001 per share. Each share of Series X Preferred Stock will be convertible into 1,000 shares of common stock at the option of the holder at any time; subject to certain limitations, including, that the holder will be prohibited from converting Series X Preferred Stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% of the total common stock then issued and outstanding immediately following the conversion of such shares of Series X Preferred Stock. In the event of the Company’s liquidation, dissolution or winding up, holders of Series X Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal (on an as-if-converted-to-common stock basis) to and in the same form as dividends actually paid on the common stock or other junior securities of the Company. Shares of Series X Preferred Stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding Series X Preferred Stock will be required to amend the terms of the Series X Preferred Stock.

SEC Accounting Series Release No. 268, *Presentation in Financial Statements of “Redeemable Preferred Stocks”* (“ASR 268”) requires equity instruments with redemption features that are not solely within the control of the issuer to be classified outside of permanent equity, often referred to as classification in “temporary equity”). The Company evaluated Series X Preferred Stock redemption features and concluded that there are no redemption features with the Series X Preferred Stock that are not solely within the control of the Company and permanent equity classification was appropriate.

Series X Preferred Stock has two (2) separate and distinct embedded features. They are: (1) optional conversion by holder and (2) redemption put feature upon fundamental transaction.

Each share of Series X Preferred Stock shall be convertible into 1,000 shares of common stock, at the option of the holder, at any time after the date of issuance. The Company evaluated the embedded optional conversion feature in accordance with the guidance under ASC 815, *Derivatives and Hedging*, and determined it is exempt from derivative accounting as the embedded feature is deemed to be indexed to the Company’s own stock and classified in stockholder’s equity if freestanding. Further, because the conversion ratio is fixed and equal to the ratio of the original exchange of 1,000

common stock to each share of Series X Preferred Stock, the Company concluded that there is no intrinsic value to the beneficial conversion feature.

Each share of Series X Preferred Stock contains redemption put features that allow the holders of the Series X Preferred Stock the right to receive, in lieu of the right to receive conversion shares, for each conversion share that would have been issuable upon such conversion immediately prior to the occurrence of an effective change in control (“Fundamental Transaction”), the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of one share of common stock. The Company evaluated the redemption put feature contained in each Series X Preferred Stock under the guidance of ASC 815, *Derivatives and Hedging*, and concluded that the embedded redemption put feature do not meet the definition of a derivative, if freestanding, under ASC 815 as net settlement could not be achieved. Accordingly, the redemption put features contained in the Series X Preferred Stock were not bi-furcated and accounted for as freestanding derivative instruments.

On June 1, 2020 and June 10, 2020, the Exchanging Stockholders converted a total of 3,285 shares of Series X Preferred Stock into 3,285,000 shares of common stock. As of June 30, 2020, 511 shares of Series X Preferred Stock remain outstanding.

Stock-Based Compensation

Total stock-based compensation expense was recognized in our condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	\$ 49	\$ 186	\$ 203	\$ 222
General and administrative	148	441	431	616
Total stock-based compensation	\$ 197	\$ 627	\$ 634	\$ 838

During the six months ended June 30, 2020, PRSUs awarded to employees totaling 55,000 shares vested and resulted in the recognition of \$204,765 in stock-based compensation expense.

Note 7. Restructuring Expense

On June 11, 2020, following the announcement regarding the topline results from the phase 2a clinical trial of OP0201, in June 2020, Novus announced that its board of directors approved a plan to reduce the size of its workforce. The workforce reduction, which was completed in June 2020, was designed to reduce the Company’s operating expenses while it is conducting a review of development and strategic alternatives. For the three months ended June 30, 2020, Novus incurred \$0.5 million in expenses related to the workforce reduction and expects to pay these amounts in the next nine months.

Total liability for restructuring expenses and their utilization are summarized as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Restructuring charges at beginning of period	\$ —	\$ —	\$ —	\$ —
Charged	490	—	490	—
Paid	—	—	—	—
Restructuring charges at end of period	\$ 490	\$ —	\$ 490	\$ —

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, 2019 included in the Annual Report on Form 10-K filed by the Company with the Securities and Exchange Commission (the "SEC") on March 16, 2020, 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. The Company has two platform technologies, a surfactant and a foam, 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"). OM is defined as 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 is a leading cause of health care visits and the most frequent reason children are prescribed antibiotics or undergo surgery in the United States. Novus also has a foam-based drug delivery technology platform, which may be developed in the future to deliver drugs into the ear, nasal, and sinus cavities.

Following the announcement regarding the topline results from the phase 2a clinical trial of OP0201, in June 2020, Novus announced that its board of directors approved a plan to reduce the size of its workforce. The workforce reduction, which was completed in June 2020, was designed to reduce the Company's operating expenses while it is conducting a review of development and strategic alternatives. For the three months ended June 30, 2020, Novus incurred \$0.5 million in expenses related to the workforce reduction and expects to pay these amounts in the next nine months.

In June 2020, Novus initiated a review of strategic alternatives that could result in changes to the Company's business strategy and future operations. As part of this process, which is being conducted in parallel with a review of development options for the Company's platform technologies, the board of directors is reviewing alternatives with the goal of maximizing stockholder value. Such options may result in a financing to continue development of the surfactant-based nasal aerosol, a company sale, merger, asset sale, in-license, out-license, or other business transaction.

Novus cannot provide any commitment regarding when or if this strategic review process will result in any type of transaction, nor any assurances that we will determine to pursue a potential sale, strategic partnership, business combination or other such arrangement. If Novus determines to pursue an alternate strategy or engage in a strategic transaction, its future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by management. Because of the significant uncertainty regarding Novus' future plans, the Company is not able to accurately predict the impact of a potential change on its business strategy and future funding requirements.

As of the date of this quarterly report on Form 10-Q, we concluded that there is substantial doubt regarding our ability to continue as a going concern for the twelve months from the date of filing of this report. 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 and potential strategic partners. As a result, it may be more difficult for us to consummate any strategic transactions and/or raise the additional financing necessary to continue to operate our business. In that circumstance, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

Surfactant Platform

The first product candidate 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”). OP0201 is 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 is also exploring the use of a dry-powder unit dose device as an alternative option for intranasal administration of DPPC and CP.

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 doses of OP0201. Results of a single-dose phase 1 trial in healthy adults (study C-001), a single-dose phase 1 trial in adults with acute otitis media (study C-004), and a 14-day phase 1 trial in healthy adults (study C-002) demonstrated the safety and tolerability of OP0201 nasal aerosol.

In June 2020, Novus announced the topline results from its phase 2a clinical trial of OP0201 nasal aerosol in infants and children with acute otitis media (study C-006). OP0201 did not achieve statistical significance for the primary efficacy endpoints in the trial, but showed positive trends with regard to resolution of middle ear effusion (56% of OP0201 patients vs. 38% of placebo patients; $p=0.07$).

Foam Platform

Novus has two product candidates developed, OP0101 and OP0102, which are foam-based product candidates 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 foam otic was the initial product candidate 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 foam otic in 353 adult and pediatric subjects, including a successful phase 2b study with a steroid-free, antibiotic-only formulation of OP0101 foam otic that was non-inferior to standard of care, but with a more favorable dosing regimen (once a day dosing instead of twice a day).

OP0102 foam otic is 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. In May 2017, Novus suspended the foam otic platform development program to focus resources on the surfactant program.

RECENT DEVELOPMENTS

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, through Piper Jaffray, up to \$9.8 million in shares of its common stock. Piper Jaffray has sold 25,218 shares of the Company’s common stock under the 2018 Prospectus.

2019 Equity Offering

On April 30, 2019, the Company agreed to sell in a registered direct offering, an aggregate 3,449,112 shares of its common stock to certain investors for gross proceeds of approximately \$10.7 million under its effective shelf registration statement on Form S-3 (File No. 333-226286). In a concurrent private placement, the Company also agreed 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 (the “Series A Warrants”) 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”). The Series B Warrants become exercisable only upon the exercise of the Series A Warrants. In addition, the Company agreed to issue to H.C. Wainwright & Co., LLC, the placement agent for the transaction, warrants to purchase up to 172,456 shares of common stock. The placement agent warrants have substantially the same terms as the Series A Warrants, except that the placement agent warrants have an exercise price equal to \$3.86875 and will expire on April 20, 2014. We refer to the registered direct offering and the concurrent private placement collectively as the “2019 Equity Offering.”

Warrant Exercise Transaction

On January 10, 2020 and January 15, 2020, the Company entered into warrant exercise agreements (the “Exercise Agreements”) with the holders (the “Holders”) of its Series A Warrants and Series B Warrants (collectively, the “Warrants”),

issued in the 2019 Equity Offering, pursuant to which the Holders agreed to exercise in cash their Warrants to purchase an aggregate of 6,898,224 shares of the Company's common stock at a reduced exercise price of \$0.715 per share, plus an additional \$0.125 per share for the issuance of the private placement warrants for gross proceeds (before placement agent fees and expenses) to the Company of approximately \$5.8 million (the "Exercise Transaction").

Under the Exercise Agreements, the Company also agreed to issue to the Holders new warrants to purchase up to 6,898,224 shares of the Company's common stock at an exercise price of \$0.72 per share, with an exercise period of five and a half years (the "Private Placement Warrants"). The Private Placement Warrants transaction subsequently closed and the Private Placement Warrants were issued on January 14, 2020 with respect to the Warrants exercised on January 10, 2020 and on or about January 17, 2020, with respect to the Warrants exercised on January 15, 2020. In addition, the Company agreed to issue to the placement agent warrants to purchase up to 344,911 shares of common stock, representing 5.0% of the aggregate number of shares of common stock issued in the Exercise Transaction. The placement agent warrants have substantially the same terms as the Private Placement Warrants issued to the Holders, except that the placement agent warrants have an exercise price equal to \$1.05. A warrant inducement expense of \$4.8 million was incurred which was determined using the Black-Scholes option pricing model and was calculated as the difference between the fair value of the Warrants prior to, and immediately after, the reduction in the exercise price on the date of repricing in addition to the fair value of the Private Placement Warrants issued.

Common Stock Exchange Agreement

On February 13, 2020, the Company entered into an exchange agreement (the "Exchange Agreement") with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P. and Biotechnology Value Trading Fund OS, L.P. (the "Exchanging Stockholders"), pursuant to which the Exchanging Stockholders exchanged (the "Exchange") 3,796,000 shares of the Company's common stock, par value \$0.001 per share, for 3,796 shares of newly designated Series X Convertible Preferred Stock (the "Series X Preferred Stock"). The Company agreed to reimburse the Exchanging Stockholders for their expenses in connection with the Exchange up to a total of \$25,000, which was recorded as operating expense in the Company's condensed consolidated statements of operations and comprehensive loss. The Exchange was completed on February 19, 2020.

On February 13, 2020, in connection with the Exchange, the Company filed a Certificate of Designation setting forth the preferences, rights and limitations of the Series X Preferred Stock with the Secretary of State of the State of Delaware. Each share of Series X Preferred Stock will be convertible into 1,000 shares of common stock at the option of the holder at any time; subject to certain limitations, including, that the holder will be prohibited from converting Series X Preferred Stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% of the total common stock then issued and outstanding immediately following the conversion of such shares of Series X Preferred Stock. In the event of the Company's liquidation, dissolution or winding up, holders of Series X Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal (on an as-if-converted-to-common stock basis) to and in the same form as dividends actually paid on the common stock or other junior securities of the Company. Shares of Series X Preferred Stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding Series X Preferred Stock will be required to amend the terms of the Series X Preferred Stock.

On June 1, 2020 and June 10, 2020, the Exchanging Stockholders converted a total of 3,285 shares of Series X Preferred Stock into 3,285,000 shares of common stock. As of June 30, 2020, 511 shares of Series X Preferred Stock remain outstanding.

COVID-19 Impact

The COVID-19 pandemic and resulting global disruptions have adversely affected our business and operations, including, but not limited to, the operations of third parties upon whom we rely. In response to public health directives and orders related to COVID-19 and based on guidance from public health officials, we have implemented work-from-home policies for our employees. The effects of executive and similar government orders, shelter-in-place orders and our work-from-home policies may negatively impact our productivity and disrupt our business. The magnitude of such effects which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

The COVID-19 pandemic and resulting global disruptions have caused significant volatility in financial and credit markets. We have utilized a range of financing methods to fund our operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding or increase the cost of funding. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect our liquidity and capital resources in the future.

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 condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these condensed consolidated 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 six months ended June 30, 2020, as compared to those disclosed in the Annual Report on Form 10-K for the year ended December 31, 2019 filed by the Company with the SEC on March 16, 2020.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended June 30, 2020 and 2019

The following table provides comparative unaudited results of operations for the three months ended June 30, 2020 and 2019 (in thousands):

	For the Three Months Ended June 30,		\$ Variance	% Variance
	2020	2019		
Operating expenses:				
Research and development	\$ 832	\$ 2,297	(1,465)	(64)%
General and administrative	1,269	1,792	(523)	(29)%
Restructuring expense	490	—	490	100%
Total operating expenses	2,591	4,089	(1,498)	(37)%
Loss from operations	(2,591)	(4,089)	1,498	(37)%
Other income (expense), net	5	(4)	9	(225)%
Net loss and comprehensive loss	<u>\$ (2,586)</u>	<u>\$ (4,093)</u>	1,507	(37)%

Research and Development Expenses

The decrease in research and development expenses of \$1,465,000 for the three month period was primarily due to decreases in clinical costs and formulation development costs for OP0201 of \$876,000 and \$417,000, respectively, as well as decreases in stock-based compensation costs of \$137,000, consulting services of \$39,000, and travel and meetings expense of \$23,000. Additionally, miscellaneous operating costs decreased \$1,000. The decreases were offset by an increase in personnel costs of \$28,000.

General and Administrative Expenses

The decrease in general and administrative expenses of \$523,000 for the three month period was primarily due to decreases in stock-based compensation costs of \$293,000, costs associated with operating a publicly traded company of \$87,000, personnel costs of \$72,000, litigation costs of \$53,000, and general operating costs of \$25,000. The decreases were offset by an increase in travel and meetings expense of \$7,000.

Restructuring Expense

On June 11, 2020, following the prior announcement of topline results of the Phase 2a Clinical Trial of OP0201 in Acute Otitis Media, the board of directors of the Company approved a reduction in force. The restructuring was completed on June 30, 2020. The Company incurred charges totaling \$490,000 for the estimated cash payments related to employee separation costs, including severance and post-employment health benefits.

Other Income (Expense), Net

The change in other income (expense), net was due to an increase in interest income of \$7,000 and a decrease in realized losses on foreign currency translation of \$2,000 for the three months ended June 30, 2020.

Comparison of the Six Months Ended June 30, 2020 and 2019

The following table provides comparative unaudited results of operations for the six months ended June 30, 2020 and 2019 (in thousands):

	For the Six Months Ended June 30,		\$ Variance	% Variance
	2020	2019		
Operating expenses:				
Research and development	\$ 2,480	\$ 5,286	(2,806)	(53)%
General and administrative	2,999	3,678	(679)	(18)%
Restructuring expense	490	—	490	100%
Total operating expenses	5,969	8,964	(2,995)	(33)%
Loss from operations	(5,969)	(8,964)	2,995	(33)%
Other income (expense), net	35	(10)	45	(450)%
Warrant inducement expense	(4,829)	—	(4,829)	100%
Net loss and comprehensive loss	<u>\$ (10,763)</u>	<u>\$ (8,974)</u>	(1,789)	20%

Research and Development Expenses

The decrease in research and development expenses of \$2.8 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, was primarily due to decreases in clinical costs and formulation development costs for OP0201 of \$1.7 million and \$1.1 million, respectively, as well as decreases in travel and meetings expense of \$69,000, stock-based compensation costs of \$18,000, and miscellaneous operating costs of \$4,000. The decreases were offset by an increase in personnel costs of \$45,000 and consulting services of \$46,000.

General and Administrative Expenses

The decrease in general and administrative expenses of \$679,000 for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily due to decreases in costs associated with operating a publicly traded company of \$345,000, stock-based compensation costs of \$186,000, litigation costs of \$160,000, general operating costs of \$45,000, and travel and meetings expense of \$7,000. The decreases were offset by an increase in personnel costs of \$64,000.

Restructuring Expense

On June 11, 2020, following the prior announcement of topline results of the Phase 2a Clinical Trial of OP0201 in Acute Otitis Media, the board of directors of the Company approved a reduction in force. The restructuring was completed on June 30, 2020. The Company incurred charges totaling \$490,000 for the estimated cash payments related to employee separation costs, including severance and post-employment health benefits.

Other Income (Expense), Net

The change in other income (expense), net was primarily related to an increase in interest income of \$37,000, a decrease of \$6,000 in realized losses on foreign currency translation, and a decrease of \$1,000 in value added tax (“VAT”) paid in Israel for the six months ended June 30, 2019.

Warrant Inducement Expense

The Company recognized warrant inducement expense of \$4.8 million as a result of the Warrant Exercise Transaction in addition to the fair value of the Private Placement Warrants issued. (See Note 6 to the condensed consolidated financial statements included elsewhere in this filing).

LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2020, we had cash of \$8.8 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 sale of warrants, 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 filing of this quarterly report on Form 10-Q.

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 our surfactant program 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 the 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 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 June 30, 2020. 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, 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 (the “Series A Warrants”) and Series B warrants to purchase up to 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”). The Series B Warrants become exercisable only upon the exercise of the Series A Warrants. In addition, the Company agreed to issue to the placement agent warrants to purchase up to 172,456 shares of common stock representing 5.0% of the aggregate number of shares of common stock sold in this offering. The placement agent warrants have substantially the same terms as the Series A Warrants issued to the investors in the concurrent private placement, except that the placement agent warrants have an exercise price equal to \$3.87, or 125% of the offering price, per share and will expire on April 30, 2024. We refer to the registered direct offering and the concurrent private placement collectively as the “2019 Equity Offering.”

On January 10, 2020 and January 15, 2020, the Company entered into warrant exercise agreements (the “Exercise Agreements”) with the holders (the “Holders”) of its Series A Warrants and Series B Warrants (collectively, the “Warrants”), issued in the 2019 Equity Offering, pursuant to which the Holders agreed to exercise in cash their Warrants to purchase an aggregate of 6,898,224 shares of the Company’s common stock at a reduced exercise price of \$0.715 per share, plus an additional \$0.125 per share for the issuance of the private placement warrants for gross proceeds (before placement agent fees and expenses) to the Company of approximately \$5.8 million (the “Exercise Transaction”).

Under the Exercise Agreements, the Company also agreed to issue to the Holders new warrants to purchase up to 6,898,224 shares of the Company’s common stock at an exercise price of \$0.72 per share, with an exercise period of five and a half years (the “Private Placement Warrants”). The Private Placement Warrants transaction subsequently closed and the Private Placement Warrants were issued on January 14, 2020 with respect to the Warrants exercised on January 10, 2020 and on or about January 17, 2020, with respect to the Warrants exercised on January 15, 2020. In addition, the Company agreed to issue to the placement agent warrants to purchase up to 344,911 shares of common stock, representing 5.0% of the aggregate number of shares of common stock issued in the Exercise Transaction. The placement agent warrants have substantially the same terms as the Private Placement Warrants issued to the Holders, except that the placement agent warrants have an exercise price equal to \$1.05.

Our primary uses of capital have been directed towards the research and development of our surfactant-based nasal product, compensation of employees, and costs associated with operating as a public company. We will continue to incur expenses during the exploration of financing options and strategic alternatives, and these expenses will increase upon continuation of research and development activity. We expect to incur substantial expenditures in the foreseeable future in order to develop and commercialize our product candidates.

On August 8, 2019, the Company received written notice (the “Notification Letter”) from The Nasdaq Stock Market LLC (“Nasdaq”) notifying the Company that it was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities maintain a minimum closing bid price of \$1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company’s common stock for the 30 consecutive business days prior to the date of the Notification Letter, the Company did not meet the minimum closing bid price requirement. The Notification Letter stated that the Company had 180 calendar days, or until February 4, 2020, to regain compliance with Nasdaq Listing Rule 5550(a)(2).

On February 6, 2020, the Company received written notice that Nasdaq determined that it is eligible for an additional 180-day extension (the “Extension Letter”), or until August 3, 2020, to regain compliance with the minimum bid price requirement. The Extension Letter does not impact the Company’s listing on the Nasdaq Capital Market at this time. To regain compliance, the closing bid price of the Company’s common stock must be at least \$1.00 per share for a minimum of 10 consecutive business days at any time prior to August 3, 2020.

On April 21, 2020, the Company received an additional notice from Nasdaq (the “Tolling Notice”), which stated that, due to current market conditions, Nasdaq has determined to toll the compliance period for the minimum bid price requirement through June 30, 2020. As a result, the new date by which the Company has to regain compliance with the minimum bid price requirement is October 19, 2020.

The Company intends to monitor the closing bid price of its common stock and consider its available options to resolve its noncompliance with the minimum bid price requirement.

On May 12, 2020, the Company’s stockholders approved and adopted an amendment to the Company’s Restated Certificate of Incorporation to effect a reverse stock split of the Company’s common stock at a ratio ranging from 1 share-for-10 shares up to a ratio of 1 share-for-30 shares, which ratio will be selected by the Company’s board of directors and set forth in a public announcement. Management may effect the reverse stock split at any time prior to December 31, 2020. If the Company’s stock price does not meet or exceed \$1.00 per share prior to the compliance deadline, management expects to effect the reverse stock split in order to regain compliance.

There can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or that the Company will otherwise be in compliance with other Nasdaq listing criteria. If the Company fails to regain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the Nasdaq Capital Market in the future and Nasdaq determines to delist its common stock, the delisting could adversely affect the market price and liquidity of the Company’s common stock and reduce its ability to raise additional capital.

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

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 Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	\$ (5,218)	\$ (8,945)
Net cash used in investing activities	—	—
Net cash provided by financing activities	5,191	9,676
Net change in cash	<u>\$ (27)</u>	<u>\$ 731</u>

Comparison of the Six Months Ended June 30, 2020 and 2019

Net cash used in operating activities for the six months ended June 30, 2020 consisted primarily of our net loss of \$10.8 million, partially offset by non-cash items consisting primarily of stock-based compensation and depreciation and amortization totaling \$726,000, as well as warrant inducement expense of \$4.8 million. Additionally, cash used in operating activities for the six months ended June 30, 2020 reflected a net decrease in cash from changes in operating assets and liabilities of \$10,000, due to a decrease in accounts payable and accrued expenses as well as a decrease in operating lease liability, offset by a decrease in prepaid expenses.

Net cash used in operating activities for the six months ended June 30, 2019 consisted primarily of our net loss of \$9.0 million, partially offset by non-cash items consisting primarily of stock-based compensation, and depreciation and amortization totaling \$928,000. Additionally, cash used in operating activities for the six months ended June 30, 2019 reflected a net decrease in cash from changes in operating assets and liabilities of \$899,000, primarily due to an increase in our prepaid expenses and a decrease in our other accrued expenses, partially offset by an increase in our accounts payable.

There was no cash provided by or used in the Company's investing activities for the six months ended June 30, 2020 and 2019.

Net cash provided by financing activities for the six months ended June 30, 2020 was comprised of \$5.2 million in net proceeds from the exercise of warrants by stockholders to purchase approximately 6.9 million shares of common stock.

Net cash provided by financing activities for the six months ended June 30, 2019 was comprised of \$9.5 million in net proceeds from the 2019 Equity Offering for the sale of approximately 3.4 million shares of Novus common stock and \$107,000 in net proceeds from the 2018 Prospectus for the sale of approximately 25,000 shares of Novus common stock.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

Contractual Obligations

Per §229.303 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.

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 June 30, 2020, 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 Securities Exchange Act of 1934, as amended (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 as of June 30, 2020 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 June 30, 2020 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.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

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.

We have incurred significant annual net operating losses in every year since our inception. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. If OP0201 or any future product candidates we develop are not successfully developed and approved, we may never generate any revenue from sales of products. The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company’s net loss for the six months ended June 30, 2020 is \$10.8 million. As of June 30, 2020, the Company had cash of \$8.8 million, working capital of \$8.7 million and an accumulated deficit of \$68.3 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 preclinical 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 have devoted a significant portion of our financial resources to the development of developing products from the surfactant platform 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). However, in June 2020, we announced our topline results from our phase 2a clinical trial of OP0201 nasal aerosol in infants and children with acute otitis media (study C-006), which did not meet the primary efficacy endpoints in the trial.

In June 2020, we announced that our board of directors had initiated a review of strategic alternatives that could result in changes to the Company’s business strategy and future operations. As part of this process, which is being conducted in parallel with a review of development options for our platform technologies, the board of directors is reviewing alternatives with the goal of maximizing stockholder value. Such options may result in a financing to continue development of the surfactant-based nasal aerosol, a company sale, merger, asset sale, in-license, out-license, or other business transaction.

If we determine to further develop product candidates from our surfactant platform, foam platform, or both, we anticipate that we will continue to incur significant expenses as we:

- conduct nonclinical and clinical development of our product candidates or any future product candidate;
- 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 conducting a review of strategic alternatives for the Company, including evaluating potential paths forward for our platform technologies that could significantly impact our future operations and financial position.

In June 2020, we announced our topline results from our phase 2a clinical trial of OP0201 nasal aerosol in infants and children with acute otitis media (study C-006), which did not meet the primary efficacy endpoints in the trial. Also in June 2020, we announced that our board of directors had initiated a review of strategic alternatives that could result in changes to the Company's business strategy and future operations. As part of this process, which is being conducted in parallel with a review of development options for our platform technologies, the board of directors is reviewing alternatives with the goal of maximizing stockholder value. Such options may result in a financing to continue development of the surfactant-based nasal aerosol, a company sale, merger, asset sale, in-license, out-license, or other business transaction. If we determine to pursue an alternate strategy or engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Pending any decision to change strategic direction, we have limited our research and development activities to manage our cash position. We cannot provide any commitment as to the timing of our determination or the strategy we may adopt. If we determine to change our business strategy or to seek to engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. If we determine to further develop any of our platform technologies, we will need to obtain substantial additional funding. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change in our business strategy and future funding requirements.

We are early in our development efforts and currently have only one product candidate in clinical development. If we are unable to successfully develop and commercialize this or any other product 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 our efforts and financial resources in product development, including funding our formulation and device development, manufacturing, nonclinical studies, and clinical trials. 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 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 any approved and marketed drug products;
- obtain and maintain adequate product pricing and reimbursement;
- develop and maintain any strategic relationships we elect to enter; 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.

The ongoing COVID-19 pandemic and actions taken in response to it may result in additional disruptions to our business operations, which could have a material adverse effect on our business.

Our business and its operations, including but not limited to ongoing or planned research and development activities, have been adversely affected by the ongoing COVID-19 pandemic, which has also caused significant disruption in the operations of third parties upon whom we rely. The COVID-19 pandemic and actions taken by governments, businesses, and individuals in response to it, including executive orders, shelter-in-place orders and work-from-home policies, have had effects that have and may continue to negatively impact productivity and disrupt our business. For example, in response to public health directives and orders, we have ceased all non-essential business travel and implemented work-from-home policies for all of our employees, resulting in reduced productivity. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could also impact personnel at the third parties on whom we are highly dependent for clinical trials as well as formulation and device development in the United States and other countries, or the timing, availability or cost of materials we use or require to conduct our business.

The COVID-19 pandemic did not materially affect our OP0201 study C-006; however, if COVID-19 continues to spread in the United States and elsewhere, we may experience additional disruptions that could severely impact our business and development activities, including, but not limited to:

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our development activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies;
- delays in procuring drug substance and/or in manufacturing drug product due to limitations in employee resources or forced furloughs at our contract manufacturing organizations; and
- delays in initiation of future clinical trials, including delays in receiving authorization from local regulatory authorities to initiate such clinical trials.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While it is not possible to predict the potential economic impact brought by COVID-19, and the duration of such impact, the pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital and negatively affect our future liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar public health emergency is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our formulation and device development efforts, healthcare systems or the global economy as a whole. However, any one or a combination of these events could have an adverse effect on our business operations, which could prevent or delay us from obtaining approval for our product candidates, as well as our ability to raise additional capital, which is necessary for us to sustain our operations.

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. Since then, operations related to development of OP0201 nasal aerosol have included arranging for third-party vendors to formulate and manufacture Good Manufacturing Procedures (“cGMP”) clinical material as well as preparing and conducting three phase 1 clinical trials and one phase 2a clinical trial. We have not yet demonstrated our ability to successfully manufacture drug product in large enough quantities and with stability to support additional clinical trials, execute pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. It can take many years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history.

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

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

We continue to conduct formulation and device development of products from the surfactant platform. We are highly dependent on third parties for formulation and device development as well as manufacturing of drug product for future clinical trials and commercial supply.

There is a risk that additional nonclinical and/or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States. and/or that subsequent studies will not match results seen in prior studies.

Reformulation work for OP0102 foam otic 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 in 2017. If

development of OP0102 foam otic is resumed, additional formulation development and clinical trials with the new foam otic combination product (antibiotic and anesthetic) will need to be conducted.

Given the early stage of development for both products, the risk of failure for both of our product candidates is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete formulation and device development for our products, conduct nonclinical trials, and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Formulation and device development, nonclinical and clinical testing are all expensive activities, difficult to design and implement, and can take years to complete. The outcome of nonclinical and clinical trials is inherently uncertain. For example, in June 2020, we announced our topline results from our phase 2a clinical trial of OP0201 nasal aerosol in infants and children with acute otitis media (study C-006), which did not meet the primary efficacy endpoints in the trial but showed positive trends with regard to resolution of middle ear effusion (56% of OP0201 patients vs. 38% of placebo patients; $p=0.07$). Failure can occur at any time during the development program, including during the clinical trial process. Further, the results of nonclinical studies and early clinical trials of our product candidates, as well as earlier generation formulations may not be predictive of the results of later-stage clinical trials. Interim results of a clinical trial do not necessarily predict final results. For instance, the results of our studies with the earlier generation OP0101 formulation may not be predictive of the results of studies conducted with OP0102 formulation, if such program is resumed. 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, safe and well-tolerated 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 EMA, or the Medicines & Healthcare Products Regulatory Agency (“MHRA”), the United Kingdom regulatory authority, will approve Clinical Trial Applications 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 FDA, EMA, MHRA or a comparable foreign regulatory authority on a trial design that we want to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- delays in completing formulation development and manufacturing as a prerequisite to commencing clinical work;
- 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 trials 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 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. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government, including the FDA. For example, a prolonged shutdown may significantly delay the FDA's ability to timely review and process any submissions we may file or cause other regulatory delays, which could materially and adversely affect our business.

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, 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 ongoing or 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;
- the patient referral practices of physicians;
- the proximity and availability of clinical trial sites for prospective patients;
- the seasonality and severity of diseases that affect enrollment (e.g. influenzae season for OM);
- 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 trials, 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 clinical trials 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. The side effect profile of the dry-powder unit dose product candidate will need to be fully established and the safety profile may differ from the safety profile of OP0201 nasal aerosol.

Risks Related to Our Financial Position and Need for Additional Capital

We have concluded and disclosed in the footnotes to our consolidated financial statements, included elsewhere within this Quarterly Report, 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 consolidated financial statements included in this Quarterly Report 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 liquidate and cease operations altogether.

We will need substantial additional funding. If we are unable to raise capital when needed, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

We expect our expenses to increase in parallel with our ongoing activities, particularly as we incur expenses relating to the exploration of strategic options intended to maximize shareholder value, seek to identify new clinical candidates and potentially seek to partner, out-license or otherwise monetize our drug candidates. If we are unable to raise capital when needed or on attractive terms, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

We will require additional capital to conduct any additional surfactant formulation and manufacturing activities, additional clinical trials and ultimately to commercialize a surfactant drug product, if approved. Because OP0201 failed to meet its primary efficacy endpoints in the phase 2a clinical trial, we may find it difficult or impossible to raise the additional capital needed to continue as a going concern. 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 development and manufacture of drug product to support nonclinical and clinical development of our product candidates;
- the extent to which we enter into additional collaboration arrangements regarding product discovery or development, or acquire or in-license products or technologies;
- our ability to establish additional collaborations with favorable terms, if at all;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting formulation development, nonclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Even if we generate positive clinical data, additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise sufficient capital to fund our planned operations, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

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.

In addition, we are authorized to issue, without stockholder approval, 5,000,000 shares of preferred stock, of which 511 shares of Series X preferred stock were issued and outstanding as of June 30, 2020. Each share of Series X preferred stock is convertible into 1,000 shares of common stock. The total number of shares of common stock issuable upon conversion of all issued shares of Series X preferred stock would be 3,796,000 shares. Each share is convertible at the option of the holder at any time, provided that the holder will be prohibited from converting into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares above a conversion blocker, which is set at 9.99% of our total common stock then issued and outstanding immediately following the conversion of such shares. If holders of shares of our Series X preferred stock elect to convert their preferred shares into common stock, such conversion would cause dilution to our current holders of common stock.

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 common stock of the company could decline. At June 30, 2020, the Company had approximately 19.4 million shares 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 United States and by other regulatory authorities outside the United States prior to commercialization in the respective regions. The process of obtaining marketing approvals, both in the United States and outside the United States, is expensive and takes several years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any country. We have no experience in filing and supporting the applications necessary to gain marketing approvals for 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 trials could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

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

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

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

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

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation that are specific to those defined by regulatory authorities in the countries where the product is approved. In the United States and other countries that follow the International Conference on Harmonization, 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 United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes intended to contain healthcare costs and modify the regulation of drug and biologic products. These and other regulatory changes 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 to the PPACA, other legislative changes have been proposed and adopted since the PPACA was enacted. In the United States, the Budget Control Act of 2011 included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. This policy was initially set to expire in fiscal year 2021 but has been extended to 2025. 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 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 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. 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 and in those jurisdictions we face the same issues as in the United States regarding difficulty and cost for us to obtain marketing approval and commercialization of our product candidates and which may affect the prices we may obtain.

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

In some countries, particularly the countries of the 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 business operations and relationships with healthcare providers, physicians, third-party payers, and customers will be subject to applicable anti-kickback, fraud and abuse and other broadly applicable healthcare laws, 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 will play a primary role in the recommendation and prescription of any product candidates for which we receive marketing approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute the products for which we receive marketing approval. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, federal and state healthcare laws are and will be applicable to our business. Such laws include, but are not limited to, the following:

- federal false claims, false statements and civil monetary penalties laws, including the federal civil False Claims Act (“FCA”), which can be enforced through civil whistleblower or qui tam actions, prohibit, among others, any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.
- the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 (“HITECH”), and their respective implementing regulations, which impose specified requirements on “covered entities,” including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information.
- the federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to track and annually report to the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U. S. Department of Health and Human Services, payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website.

- analogous state, local or foreign laws, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require licensure or registration by sales and marketing agents of a pharmaceutical company; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA.

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. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. For example, in June 2018, California enacted the California Consumer Privacy Act of 2018 (the “CCPA”), which took effect on January 1, 2020. The CCPA gives California residents the right to access and require deletion of their personal information, the right to opt out of certain personal information sharing, and the right to detailed information about how their personal information is collected, used and shared. The CCPA provides civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a wave of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business. Several foreign jurisdictions, including the EU, its member states, the United Kingdom, Japan and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. Additionally, certain countries have passed or are considering passing laws that require local data residency and/or restrict the international transfer of data. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. 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, disgorgement, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Laws, restrictions, and other regulatory measures are also imposed by anti-kickback, fraud and abuse, and other healthcare laws and regulations in international jurisdictions, and in those jurisdictions we face the same issues as in the United State regarding exposure to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

We depend on our information technology systems and those of our third-party collaborators, service providers, contractors or consultants. Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our internal technology systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, natural disasters, terrorism, war and telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, persons inside our organizations (including employees or contractors), loss or theft, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related incidents.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

European data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.

We may collect, process, use or transfer personal information from individuals located in the European Economic Area in connection with our business, including in connection with conducting clinical trials in the EEA. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Economic Area. The collection and use of personal health data in the European Economic Area is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679) (the “GDPR”), along with other European Union and country-specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals’ requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Economic Area and other states in the European Economic Area may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

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. There are several large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a number of companies developing or marketing treatments for AOE, including many major pharmaceutical and biotechnology companies. We expect that OP0102 will face competition from numerous FDA-approved therapeutics, including CIPRODEX® and numerous other branded and generic ear anti-infectives.

In OM, there are currently no drug therapies approved for the treatment or prevention of OM. We expect that OP0201 will compete primarily with a surgery where the tympanic membrane is perforated to improve drainage and ventilation of the middle ear (myringotomy or tympanostomy tube insertions) as a means of preventing recurrent or chronic OM. We may also compete with a medical device that uses a small intranasal balloon inserted into the ET to ventilate the ET in patients with ETD of a particular type. Surgery 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 used in conjunction with OP0201.

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

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

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

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

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payers, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Increased expense is incurred to cover costs of health outcome focused research used to generate data necessary to justify the value of our products in order to secure reimbursement. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

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

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

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

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

We currently hold \$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 several 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 that we may enter 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, 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 trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.

We have utilized, and intend to continue utilizing, third parties to formulate, manufacture, package, and distribute clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have sole suppliers for one or more of our active pharmaceutical ingredients ("API"), and a different sole manufacturer for each of our product candidates. In addition, these materials are custom-made and available from only a limited number of sources. In particular, there may be a limited supply source for APIs for OPO201 or other potential product candidates. Although we believe that our third-party suppliers maintain a significant supply of APIs on hand, any sustained disruption in this supply could adversely affect our operations. We do not have any long-term agreements in place with our current API suppliers. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with regulatory requirements and our specifications. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing approved product candidates could negatively affect our sales revenues, as well as delay our clinical trials.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval. Despite drug substance and product risk management, this reliance on third parties presents a risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. In addition, the operations of these third parties have been and may continue to be significantly disrupted by the ongoing COVID-19 pandemic. Any delay or 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 United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Additionally, macro-economic conditions may adversely affect these third parties, causing them to suffer liquidity or operational problems. If a key third-party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer.

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

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

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 United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and internationally that are related to our novel technologies and product candidates. This patent portfolio includes issued patents and pending patent applications covering pharmaceutical 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 United States. For example, India and China do not allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the EU, the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), was signed into law. The Leahy-Smith Act includes a number of significant changes to 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 United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our own.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with several 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 surfactant platform through a license agreement with Otodyne, Inc. and may in the future enter into other license agreements with third parties for other intellectual property rights or assets. These license agreements may impose various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates than if we had developed the licensed technology internally.

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

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

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

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

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license, or 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 NDAs or similar agreements entered into by the Company may not be with all relevant parties, or adequately protect the confidentiality of our trade secrets. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

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

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

We 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.

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.

We are not currently in compliance with the continued listing requirements for Nasdaq. If the price of our common stock continues to trade below \$1.00 per share for a sustained period or we do not meet other continued listing requirements, our common stock may be delisted from the Nasdaq Capital Market, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital.

On August 8, 2019, we received written notice (the "Notification Letter") from The Nasdaq Stock Market LLC ("Nasdaq") notifying us that the Company was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities maintain a minimum closing bid price of \$1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company's common stock for the 30 consecutive business days prior to the date of the Notification Letter, we did not meet the minimum closing bid price requirement. The Notification Letter stated that we had 180 calendar days, or until February 4, 2020, to regain compliance with Nasdaq Listing Rule 5550(a)(2).

On February 6, 2020, we received written notice that Nasdaq determined that we are eligible for an additional 180-day extension (the “Extension Letter”), or until August 3, 2020, to regain compliance with the minimum bid price requirement. The Extension Letter does not impact the Company’s listing on the Nasdaq Capital Market at this time. To regain compliance, the closing bid price of the Company’s common stock must be at least \$1.00 per share for a minimum of 10 consecutive business days at any time prior to August 3, 2020.

On April 21, 2020, the Company received an additional notice from Nasdaq (the “Tolling Notice”), which stated that, due to current market conditions, Nasdaq has determined to toll the compliance period for the minimum bid price requirement through June 30, 2020. As a result, the new date by which the Company has to regain compliance with the minimum bid price requirement is October 19, 2020.

We intend to monitor the closing bid price of our common stock and consider our available options to resolve our noncompliance with the minimum bid price requirement.

On May 12, 2020, our stockholders approved and adopted an amendment to our Restated Certificate of Incorporation to effect a reverse stock split of our common stock at a ratio ranging from 1 share-for-10 shares up to a ratio of 1 share-for-30 shares, which ratio will be selected by our board of directors and set forth in a public announcement. Management may affect the reverse stock split at any time prior to December 31, 2020. If our stock price does not meet or exceed \$1.00 per share prior to the compliance deadline, management expects to effect the reverse stock split in order to regain compliance.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or we will otherwise be in compliance with other Nasdaq listing criteria. If we fail to regain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the Nasdaq Capital Market in the future and Nasdaq determines to delist our common stock, the delisting could adversely affect the market price and liquidity of our common stock and reduce our ability to raise additional capital.

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

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

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

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

Our executive officers and directors, combined with our principal stockholders, beneficially own shares representing approximately 30.0% of our capital stock as of June 30, 2020. 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.

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

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

Ensuring that we will have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the United States ("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 DGCL, which prohibits a person who owns in excess of 15% of its outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

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

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Index

Exhibit Number	Description
31.1*	<u>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.</u>
31.2*	<u>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.</u>
32.1*	<u>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.</u>
32.2*	<u>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.</u>
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: August 13, 2020

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

Date: August 13, 2020

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

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: August 13, 2020

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

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: August 13, 2020

By: /s/ Jon S. Kuwahara

Jon S. Kuwahara

Senior Vice President Finance & Administration
(Principal Financial and Accounting Officer)

**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 June 30, 2020 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: August 13, 2020

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

**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 June 30, 2020 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: August 13, 2020

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