Novus Therapeutics Reports Fourth Quarter and Full-Year 2018 Financial Results and Provides Clinical Updates

March 28, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Mar. 28, 2019-- Novus Therapeutics, Inc. (NASDAQ: NVUS), a specialty pharmaceutical company focused on developing products for patients with disorders of the ear, nose, and throat (ENT), today announced financial results for the quarter and year ended December 31, 2018 and provided updates on the OP0201 development program.

"We made significant progress on the OP0201 program in 2018," said Gregory J. Flesher, CEO of Novus Therapeutics. "We completed formulation development, initiated our first of several planned clinical trials, and filed a new patent application for OP0201. In addition, we expanded our organization by hiring talented individuals to fill key R&D and G&A positions. We now have four OP0201 clinical trials ongoing, including an exploratory phase 2a study in children with acute otitis media. We look forward to sharing the results of all of these studies in 2019."

OP0201 Development Updates

- Study C-001 is a phase 1 clinical trial designed to evaluate safety, tolerability, and Eustachian tube ("ET") function following a single intranasal dose of OP0201 in 16 healthy adults. The randomized, double-blind, placebo-controlled, cross-over trial explores the effects of a 20 mg dose of OP0201 on ET function. Assessment of ET function is captured using continuous tympanic impedance while subjects are exposed to changes in atmospheric pressure produced within a hyperbaric/hypobaric chamber. Data from this study is expected to be available in Q2 2019.
- Study C-002 is a phase 1 clinical trial designed to evaluate safety and tolerability of daily intranasal administration of OP0201 over 14 consecutive days in 30 healthy adults. The randomized, double-blind, placebo-controlled, parallel-group, dose-escalation trial includes a 30 mg per day dose (Cohort A) and 60 mg per day dose (Cohort B) of OP0201. Data from this study is expected to be available in Q2 2019.
- Study C-004 is a phase 1 clinical trial designed to evaluate safety, tolerability, and relief of ear pain over a 60-minute observation period following a single intranasal dose of OP0201 in 24 adults with acute otitis media. The randomized, double-blind, placebo-controlled, parallel-group trial explores the effects of a 20 mg intranasal dose of OP0201. Assessment of pain relief is captured utilizing a Visual Analog Scale (VAS), Numeric Rating Scale (NRS-11), Patient Global Impression of Change (PGIC), and Clinical Global Impressions Scale: Global Improvement (CGI-I). Data from this study is expected to be available in April 2019.
- Study C-006 is an exploratory phase 2a clinical trial designed to evaluate safety, tolerability, and efficacy of daily intranasal administration of OP0201 over 10 consecutive days in up to 50 pediatric patients, 6 to 24 months of age, with acute otitis media. The randomized, double-blind, placebo-controlled, parallel-group trial explores the effects of a 20 mg per day dose of OP0201 as an adjunct to oral antibiotics. Patients will receive 10 days of treatment and will be followed for up to 30 days, during which multiple endpoints will be explored. Enrollment is currently ongoing with data expected in 2H 2019.

Fourth Quarter and Full-Year 2018 Financial Results

For the three-month period ended December 31, 2018, Novus reported a net loss of $4.6 million, or $0.49 loss per share, compared to a net loss of $2.1 million, or $0.30 loss per share, for the same period in 2017. For the twelve-month period ended December 31, 2018, Novus reported a net loss of $14.1 million, or $1.56 loss per share, as compared to a net loss of $13.1 million, or $2.30 loss per share, for the same period in 2017. The company had approximately $13.0 million in cash and cash equivalents as of December 31, 2018.

Research and development (R&D) expenses were $2.7 million during the three-month period ended December 31, 2018, compared to $0.5 million for the same period in 2017. R&D expenses for the twelve-month period ended December 31, 2018 were $6.8 million, compared to $2.0 million for the same period in 2017. The increase in R&D expenses for calendar 2018 was primarily due to an increase in formulation and device development costs of $2.1 million, an increase in clinical development costs of $1.7 million, an increase in consulting costs of $242,000 related to the advancement of our OP0201 program and increased personnel costs of $713,000 related to additional headcount. We expect R&D expenses to increase in subsequent periods as we advance our OP0201 program.

General and administrative (G&A) expenses were $1.8 million during the three-month period ended December 31, 2018, compared to $1.6 million for the same period in 2017. G&A expenses for the twelve-month period ended December 31, 2018 were $7.2 million, compared to $11.1 million for the same period in 2017. The decrease in G&A expenses for calendar 2018 was primarily due to a reduction of $5.1 million in merger related expenses, partially offset by an increase of $659,000 in administrative costs associated with operating a public company and increased personnel costs of $511,000 related to additional headcount. We expect similar G&A expenses in 2019, but an increase in subsequent periods.

About OP0201

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 ET, which is a small tube that connects the middle ear cavity 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 is intended to promote

‘de-sticking’ of the ET so that ventilation of the middle ear may occur.

About Novus Therapeutics

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

Forward-Looking Statements

This press release contains forward-looking statements that involves substantial risks and uncertainties. Any statements about the company’s future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” “estimates,” “intends,” “predicts,” “projects,” “targets,” “looks forward,” “could,” “may,” and similar expressions, constitute forward -looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding: expectations regarding the timing for the commencement and completion of product development or clinical trials, including the four ongoing OP0201 clinical trials; expectations regarding the success of clinical trials; the rate and degree of market acceptance and clinical utility of the company’s products; the company’s commercialization, marketing and manufacturing capabilities and strategy; the company’s intellectual property position and strategy; the company’s ability to identify additional products or product candidates with significant commercial potential; the company’s estimates regarding expenses, future revenue, capital requirements and needs for additional financing; developments relating to the company’s competitors and industry; and the impact of government laws and regulations. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the ability to develop commercially viable product formulations; the sufficiency of the company’s cash resources; the ability to obtain necessary regulatory and ethics approvals to commence additional clinical trials; whether data from early clinical trials will be indicative of the data that will be obtained from future clinical trials; whether the results of clinical trials will warrant submission for regulatory approval of any investigational product; whether any such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies and, if we are able to obtain such approval for an investigational product, whether it will be successfully distributed and marketed. These risks and uncertainties, as well as other risks and uncertainties that could cause the company’s actual results to differ significantly from the forward -looking statements contained herein, are discussed in our quarterly, annual, and other filings with the SEC, which can be found at www.sec.gov. Any forward-looking statements contained in this press release 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.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	December 31,	
	2018	**2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,972	$ 17,233
Restricted cash	—	70
Prepaid expenses and other current assets	1,304	1,697
Total current assets	14,276	19,000
Property and equipment, net	14	25
Goodwill	1,867	1,867
Other assets	869	—
Total assets	$ 17,026	$ 20,892
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Accounts payable	$ 689	$ 418
Accrued severance	—	668
Accrued expenses and other liabilities	1,845	354
Total liabilities	2,534	1,440
Commitments and contingencies		
Stockholders’ equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at December 31, 2018 and 2017	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2018 and 2017; 9,422,143 and 7,110,414 shares issued and outstanding at December 31, 2018 and 2017, respectively	9	7
Additional paid-in capital	56,054	46,951
Accumulated deficit	(41,571)	(27,506)
Total stockholders’ equity	14,492	19,452
Total liabilities and stockholders’ equity	$ 17,026	$ 20,892

NOVUS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,	
	2018	**2017**
Operating expenses		
Research and development	$ 6,817	$ 2,022
General and administrative	7,243	11,099
Total operating expenses	14,060	13,121
Loss from operations	(14,060)	(13,121)
Other income (expense), net	(5)	5
Net loss and other comprehensive loss	$ (14,065)	$ (13,116)
Net loss per share, basic and diluted	$ (1.56)	$ (2.30)
Weighted-average common shares outstanding, basic and diluted	9,005,352	4,677,610

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