Novus Therapeutics Reports Second Quarter 2018 Financial Results

August 7, 2018

IRVINE, Calif.--(BUSINESS WIRE)--Aug. 7, 2018-- 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 ended June 30, 2018.

"We continue to make progress on the OP-02 development program and look forward to initiating our clinical program this year," said Gregory J. Flesher, CEO of Novus Therapeutics, Inc. "We had a productive Type C meeting with the FDA during this quarter. The FDA confirmed that development of OP-02 for separate otitis media treatment and prevention indications would be acceptable. We also obtained guidance on our planned phase 1 healthy volunteer study and subsequent studies in patients to support these indications. We look forward to sharing results from the phase 1 program in 2019."

Second Quarter 2018 Financial Results

For the three-months ended June 30, 2018, Novus reported a net loss of $3.2 million, or $0.34 per share, compared to a net loss of $6.7 million, or $1.32 per share, for the same period in 2017. For the six-months ended June 30, 2018, Novus reported a net loss of $6.0 million, or $0.70 per share, compared to a net loss of $8.0 million, or $2.51 per share, for the same period in 2017. The company had $19.2 million in cash and cash equivalents as of June 30, 2018.

Research and development (R&D) expenses were $1.3 million during the three-months ended June 30, 2018, compared to $0.5 million for the same period in 2017. For the six-month ended June 30, 2018, R&D expenses were $2.4 million, compared to $1.0 million for the same period in 2017. The increase in R&D expenses for both periods was primarily due to an increase in formulation development costs for OP-02, consulting expenses, and hiring of additional R&D employees. We expect R&D expenses to increase in subsequent periods due to the initiation of multiple OP-02 clinical trials.

General and administrative (G&A) expenses were $1.9 million during the three-months ended June 30, 2018, compared to $6.1 million for the same period in 2017. For the six-month ended June 30, 2018, G&A expenses were $3.6 million, compared to $7.0 million for the same period in 2017. The decrease in G&A expenses for both periods was primarily due to non-recurring merger-related expenses from 2017 and a decrease in rent expense, partially offset by an increase in insurance, stock-based compensation, professional fees, and other administrative costs associated with operating a public company as well as costs related to the Tokai shareholder litigation.

Anticipated Milestones

- Q4 2018 – Initiate phase 1 study in healthy adults (safety/tolerability)
- 1H 2019 – Initiate phase 1 study in patients with otitis media with effusion (explore efficacy)
- 1H 2019 – Initiate phase 1 study in patients with acute otitis media (explore efficacy)
- 1H 2019 – Topline data from phase 1 studies

About OP-02

OP-02 is being developed as a potential first-in-class treatment option for otitis media ("OM"), which is often caused by Eustachian tube dysfunction ("ETD"). OP-02 is a drug-device combination product comprised of a proprietary formulation surfactant (dipalmitoylphosphatidylcholine or "DPPC") and a spreading agent (cholesteryl palmitate or "CP") suspended in propellant. The product is administered intranasally via a pressurized metered-dose inhaler ("pMDI") and is intended to be used to restore the normal physiologic activity of the Eustachian tube ("ET"), which is the small tube that connects the middle ear to the back of the nasopharynx. Together DPPC and CP are designed to 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, OP-02 is intended to promote 'de-sticking' of the ET so that ventilation and drainage of the middle ear may occur.

About Novus Therapeutics

Novus Therapeutics, Inc. ("Novus") is a specialty pharmaceutical company focused on developing products for disorders of the ear, nose, and throat ("ENT"). Novus has two technologies, each that has the potential to be developed for multiple ENT indications. Novus' lead product candidate (OP-02) is a surfactant-based, combination drug product being developed as a potential first-in-class treatment option for patients at risk for, or with, otitis media ("OM" or middle ear inflammation with or without infection). Globally, OM affects more than 700 million adults and children every year, with over half of cases occurring in children under five years of age. OM is one of the most common disorders seen in pediatric practice, and in the United States 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 (OP-01), 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

Any statements in this press release about the company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, the review of strategic alternatives and the outcome of such review and other statements containing the words "believes," "anticipates," "plans," "expects," "may," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, expectations regarding the timing for the commencement and completion of our clinical trials, manufacture drug product and our ability to accelerate the development of our drug candidates. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the sufficiency of the company's cash resources; the ability to timely develop and manufacture clinical batches of our study drugs; the ability

to obtain necessary 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, 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, it will be successfully distributed and marketed. 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)

	June 30, 2018	December 31, 2017
	(Unaudited)	
ASSETS		
Current assets:		
Cash	$ 19,189	$ 17,233
Restricted cash	—	70
Prepaid expenses and other current assets	1,889	1,697
Total current assets	21,078	19,000
Property and equipment, net	20	25
Goodwill	1,867	1,867
Total assets	$ 22,965	$ 20,892
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 706	$ 418
Accrued severance	224	668
Accrued expenses and other liabilities	522	354
Total liabilities	1,452	1,440
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2018 and December 31, 2017; 9,407,024 and 7,110,414 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	9	7
Additional paid-in capital	55,005	46,951
Accumulated deficit	(33,501)	(27,506)
Total stockholders' equity	21,513	19,452
Total liabilities and stockholders' equity	$ 22,965	$ 20,892

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	$ 1,329	$ 533	$ 2,426	$ 1,012
General and administrative	1,860	6,133	3,558	7,039
Total operating expenses	3,189	6,666	5,984	8,051
Loss from operations	(3,189)	(6,666)	(5,984)	(8,051)
Other income (expense), net	—	4	(11)	15
Net loss and comprehensive loss	$ (3,189)	$ (6,662)	$ (5,995)	$ (8,036)
Net loss per share, basic and diluted	$ (0.34)	$ (1.32)	$ (0.70)	$ (2.51)
Weighted-average common shares outstanding, basic and diluted	9,407,024	4,154,842	8,582,723	2,270,907

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Source: Novus Therapeutics, Inc.

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