



Novus Therapeutics Reports First Quarter 2018 Financial Results

May 11, 2018

IRVINE, Calif.--(BUSINESS WIRE)--May 11, 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 March 31, 2018 and provided a corporate update.

"We are excited by the ongoing progress being made with OP-02, our novel and potential first-in-class treatment option for otitis media," said Gregory J. Fleisher, CEO of Novus Therapeutics, Inc. "The next step for the program is to manufacture drug product, which we expect to complete in the coming months. This product will allow us to initiate our first-in-human clinical studies with OP-02 in the second half of 2018. In addition, we strengthened our financial position during the quarter with the completion of our at-the-market facility, bringing our cash and cash equivalents to \$22.5 million as of March 31, 2018."

First Quarter 2018 Financial Results

For the three-month period ended March 31, 2018, Novus reported a net loss of \$2.8 million, or \$0.36 loss per share, compared to a net loss of \$1.4 million, or \$0.59 loss per share, for the same period in 2017. The company had \$22.5 million in cash and cash equivalents as of March 31, 2018.

Research and development (R&D) expenses were \$1.1 million during the three-month period ended March 31, 2018, compared to \$0.5 million for the same period in 2017. R&D expenses were higher in 2018 primarily due to increased spending on the surfactant program (OP-02). We expect research and development expenses to increase in subsequent periods due to the initiation of OP-02 clinical trials.

General and administrative (G&A) expenses were \$1.7 million during the three-month period ended March 31, 2018, compared to \$0.9 million for the same period in 2017. G&A expenses were higher in 2018 primarily due to an increase in administrative costs associated with operating a public company, ongoing legal costs related to Tokai's shareholder lawsuits, and stock-based compensation.

Anticipated Milestones

- Mid-2018 - Manufacture OP-02 drug product (cGMP)
- 2H 2018 - Initiate OP-02 phase 1 study in healthy adults (safety/tolerability)
- 1H 2019 - Initiate OP-02 phase 1 study in children with otitis media with effusion (explore efficacy)
- 1H 2019 - Initiate OP-02 phase 1 study in adults with acute otitis media (explore efficacy)
- 1H 2019 - Topline data from phase 1 studies

About OP-02

OP-02 is a drug-device combination product comprised of a novel formulation of the surfactant dipalmitoylphosphatidylcholine (DPPC) and the spreading agent cholesteryl palmitate (CP) suspended in a propellant. The product is administered intranasally via a metered dose inhaler and is intended to be used to restore the normal physiologic activity of the Eustachian tube (ET). Together DPPC and CP 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 promotes 'de-sticking' of the ET so that ventilation and drainage of the middle ear may occur.

About Novus Therapeutics

Novus Therapeutics 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. The company's lead product (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") (middle ear inflammation with or without infection). Globally, OM affects more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice, and in the United States is the most frequent reason children are prescribed antibiotics and undergo surgery. 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, our ability to 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)

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	\$ 22,523	\$ 17,233
Restricted cash	—	70
Prepaid expenses and other current assets	<u>1,505</u>	<u>1,697</u>
Total current assets	24,028	19,000
Property and equipment, net	22	25
Goodwill	<u>1,867</u>	<u>1,867</u>
Total assets	<u>\$ 25,917</u>	<u>\$ 20,892</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 449	\$ 418
Accrued severance	428	668
Accrued expenses and other liabilities	<u>742</u>	<u>354</u>
Total liabilities	1,619	1,440
Commitments and contingencies		
Stockholders' equity		
Common stock, \$0.001 par value, 200,000,000 shares authorized at March 31, 2018 and December 31, 2017; and 9,407,024 and 7,110,414 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	9	7
Additional paid-in capital	54,601	46,951
Accumulated deficit	<u>(30,312)</u>	<u>(27,506)</u>
Total stockholders' equity	<u>24,298</u>	<u>19,452</u>
Total liabilities and stockholders' equity	<u>\$ 25,917</u>	<u>\$ 20,892</u>

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

	Three Months Ended March 31, 2018	March 31, 2017
Operating expenses		
Research and development	\$ 1,097	\$ 479
General and administrative	<u>1,698</u>	<u>906</u>
Total operating expenses	<u>2,795</u>	<u>1,385</u>
Loss from operations	(2,795)	(1,385)
Other income (expense), net	<u>(11)</u>	<u>11</u>
Net loss and other comprehensive loss	<u>\$ (2,806)</u>	<u>\$ (1,374)</u>
Net loss per share, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.59)</u>
Weighted-average common shares outstanding, basic and diluted	<u>7,749,263</u>	<u>413,635</u>

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Source: Novus Therapeutics, Inc.

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