Novus Therapeutics Reports Fourth Quarter and Full-Year 2017 Financial Results and Provides Corporate Update

April 2, 2018

IRVINE, Calif.--(BUSINESS WIRE)--Apr. 2, 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 and year ended December 31, 2017 and provided a corporate update.

"The past year was a productive year for us," said Gregory J. Flesher, CEO of Novus Therapeutics. "We completed the merger with Tokai Pharmaceuticals, Inc. and embarked on a mission to develop a novel, first-in-class treatment option for otitis media. Over the last several months we have made good progress on OP-02 and now plan to initiate our phase 1 clinical program in the second half of this year."

Fourth Quarter and Full-Year 2017 Financial Results

For the three-month period ended December 31, 2017, Novus reported a net loss of $2.1 million, or $0.30 loss per share, compared to a net loss of $1.5 million, or $0.57 loss per share, for the same period in 2016. For the twelve-month period ended December 31, 2017, Novus reported a net loss of $13.1 million, or $2.30 loss per share, as compared to a net loss of $5.7 million, or $2.46 loss per share, for the same period in 2016. The company had $17.2 million in cash and cash equivalents as of December 31, 2017.

Research and development (R&D) expenses were $0.5 million during the three-month period ended December 31, 2017, compared to $0.9 million for the same period in 2016. R&D expenses for the twelve-month period ended December 31, 2017 were $2.0 million, compared to $3.2 million for the same period in 2016. R&D expenses were lower in 2017 primarily due to decreased spending on the foam program (OP-01), offset by wind down costs incurred for legacy Tokai programs. We expect research and development expenses to increase in subsequent periods as we advance our surfactant program (OP-02).

General and administrative (G&A) expenses were $1.6 million during the three-month period ended December 31, 2017, compared to $0.6 million for the same period in 2016. G&A expenses for the twelve-month period ended December 31, 2017 were $11.1 million, compared to $1.9 million for the same period in 2016. G&A expenses were higher in 2017 primarily due to the recognition of merger related expenses, an increase in administrative costs associated with operating a public company, and the ongoing legal costs related to Tokai's stockholder litigation.

Recent Events

In March 2018, the company announced that it had concluded its offering of common stock under its "at-the-market" offering facility. The company raised approximately $8.5 million in gross proceeds under the facility.

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 - Data from phase 1 studies

About OP-02

OP-02 is a drug-device combination product comprised of a novel formulation of dipalmitoylphosphatidylcholine (DPPC) and 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 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)

	December 31,	
	2017	**2016**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,233	$ 1,103
Restricted cash	70	14
Prepaid expenses and other current assets	1,697	33
Total current assets	19,000	1,150
Property and equipment, net	25	31
Goodwill	1,867	—
Other assets	—	15
Total assets	$ 20,892	$ 1,196
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable	$ 418	$ 338
Accrued severance	668	—
Accrued expenses and other liabilities	354	113
Convertible notes	—	3,447
Total liabilities	1,440	3,898
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at December 31, 2017; $0.001 par value, 44,140,630 shares authorized and 19,533,331 shares issued and outstanding at December 31, 2016 (1)	—	19
Common stock, $0.001 par value, 200,000,000 shares authorized and 7,110,414 shares issued and outstanding at December 31, 2017; $0.001 par value, 31,476,614 shares authorized and 394,306 shares issued and outstanding at December 31, 2016 (2)	7	—
Additional paid-in capital	46,951	11,378
Receipts on account of preferred stock	—	291
Accumulated deficit	(27,506)	(14,390)
Total stockholders' equity (deficit)	19,452	(2,702)
Total liabilities and stockholders' equity (deficit)	$ 20,892	$ 1,196

(1) Number of shares as of December 31, 2016, has been retroactively adjusted to reflect the effect of the conversion ratio of the Reverse Merger consummated on May 9, 2017.

(2) Number of shares has been retroactively adjusted to reflect the effect of the conversion ratio of the Reverse Merger consummated on May 9, 2017, and the reverse stock-split effected on May 11, 2017.

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

	Year Ended December 31,	
	2017	**2016**
Operating expenses		
Research and development	$ 2,022	$ 3,191

General and administrative	11,099	1,937
Total operating expenses	13,121	5,128
Loss from operations	(13,121)	(5,128)
Other income (expense), net	5	(527)
Net loss and other comprehensive loss	$ (13,116)	$ (5,655)
Net loss per share, basic and diluted	$ (2.30)	$ (2.46)
Weighted-average common shares outstanding, basic and diluted	4,677,610	382,747

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