

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

May 11, 2018
Date of Report
(Date of earliest event reported)

Novus Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36620
(Commission
File Number)

20-1000967
(IRS Employer
Identification No.)

1990 MacArthur Blvd., Suite 550
Irvine, California 92612
(Address of principal executive offices, including Zip Code)

(949) 238-8090
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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.

Item 2.02 **Results of Operations and Financial Condition.**

On May 11, 2018, Novus Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2018. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits:

99.1 [Press Release of Novus Therapeutics, Inc., dated May 11, 2018](#)

SIGNATURE

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 hereunto duly authorized.

Novus Therapeutics, Inc.

Date: May 11, 2018

By: /s/ Gregory J. Flesher
Name: Gregory J. Flesher
Title: Chief Executive Officer



Novus Therapeutics Reports First Quarter 2018 Financial Results

Friday May 11, 2018 6:15 AM PDT

IRVINE, Calif. -- (BUSINESS WIRE) -- 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. Flesher, 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
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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	1,505	1,697
Total current assets	24,028	19,000
Property and equipment, net	22	25
Goodwill	1,867	1,867
Total assets	\$ 25,917	\$ 20,892
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 449	\$ 418
Accrued severance	428	668
Accrued expenses and other liabilities	742	354
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	(30,312)	(27,506)
Total stockholders' equity	24,298	19,452
Total liabilities and stockholders' equity	\$ 25,917	\$ 20,892

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

Investor Contacts

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