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

November 13, 2018
Date of Report
(Date of earliest event reported)

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

Delaware	**001-36620**	**20-1000967**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

19900 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 November 13, 2018, Novus Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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 November 13, 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: November 13, 2018

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

Exhibit 99.1

Novus Therapeutics Reports Third Quarter 2018 Financial Results

November 13, 2018 at 8:00 AM Eastern Time

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 September 30, 2018.

“This is an exciting time for the company as we transition into the clinic with a potential first-in-class treatment option for otitis media. We continued to advance the OP-02 program during the quarter and are now positioned to achieve several milestones over the next few quarters,” said Gregory J. Flesher, CEO of Novus Therapeutics. “We have successfully manufactured and released OP-02 drug product for our phase 1 safety and tolerability study in healthy adults. We expect to enroll the first subject in the coming weeks.”

“We recently received IRB approval to initiate additional phase 1 safety and exploration of efficacy studies; a study in adults with acute otitis media and a pharmacodynamic study in healthy adults. We expect to begin enrolling these studies in 2019,” concluded Mr. Flesher.

Anticipated Milestones in Q4 2018 and 1H 2019

- Q4 2018 – Initiate phase 1 study in healthy adults (safety/tolerability)
- Q4 2018 – Initiate phase 1 study in patients with acute otitis media (explore efficacy)
- Q1 2019 – Initiate phase 1 study in healthy adults (pharmacodynamic effects)
- 1H 2019 – Initiate phase 1 study in patients with otitis media with effusion (explore efficacy)
- 1H 2019 – Topline data from phase 1 studies

Financial Results for Third Quarter 2018

For the three-months ended September 30, 2018, Novus reported a net loss of $3.5 million, or $0.37 per share, compared to a net loss of $3.0 million, or $0.43 per share, for the same period in 2017.

For the nine-months ended September 30, 2018, Novus reported a net loss of $9.5 million, or $1.07 per share, compared to a net loss of $11.0 million, or $2.25 per share, for the same period in 2017.

The company had $16.3 million in cash and cash equivalents as of September 30, 2018. Novus believes that its current cash will be sufficient to complete the planned phase I program.

Research and Development (R&D)

R&D expenses were $1.7 million during the three-months ended September 30, 2018, compared to $0.5 million for the same period in 2017. The increase for the three-month period was primarily due to an increase in formulation development costs for OP-02 of $658,000, an increase in clinical related costs for OP-02 of $359,000, and an increase in personnel related costs of $117,000.

For the nine-months ended September 30, 2018, R&D expenses were $4.1 million, compared to $1.5 million for the same period in 2017. The increase for the nine-month period was primarily due to an increase in formulation development costs for OP-02 of $1.9 million, an increase in clinical related costs for OP-02 of $382,000, an increase in personnel related costs of $266,000, and an increase in travel and meetings costs of $132,000, partially offset by a decrease in merger-related severance expenses of $155,000.

The company expects R&D expenses to increase in subsequent periods as we advance our OP-02 program.

General and administrative (G&A)

G&A expenses were $1.8 million during the three-months ended September 30, 2018, compared to $2.4 million for the same period in 2017. The decrease for the three-month period was primarily due to $619,000 in non-recurring merger-related expenses incurred in 2017 and a $68,000 decrease in personnel related costs, partially offset by increases in stock-based compensation expenses of $56,000 and patent legal fees of $47,000.

For the nine-months ended September 30, 2018, G&A expenses were $5.4 million, compared to $9.5 million for the same period in 2017. The decrease for the nine-month period was primarily due to $5.0 million in non-recurring merger-related expenses incurred in 2017 and a decrease in rent expense of $316,000, partially offset by an increase of $721,000 in insurance, professional fees, board of directors expense, and other administrative costs associated with operating a public company, as well as increases in stock-based compensation expenses of $335,000 and Tokai litigation and patent legal costs of $175,000.

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 patients with 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

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,” “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; 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 annual report on Form 10-K for the year ended December 31, 2017, as well as subsequent filings with the SEC which can be found at www.sec.gov. Any forward-looking statements contained in this presentation 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.

Source: Novus Therapeutics, Inc.

Investor Contacts

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NOVUS THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash	$ 16,324	$ 17,233
Restricted cash	—	70
Prepaid expenses and other current assets	786	1,697
Total current assets	17,110	19,000
Property and equipment, net	17	25
Goodwill	1,867	1,867
Other assets	934	—
Total assets	$ 19,928	$ 20,892
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 751	$ 418
Accrued severance	90	668
Accrued expenses and other liabilities	762	354
Total liabilities	1,603	1,440
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2018 and December 31, 2017; 9,422,143 and 7,110,414 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	9	7
Additional paid-in capital	55,313	46,951
Accumulated deficit	(36,997)	(27,506)
Total stockholders' equity	18,325	19,452
Total liabilities and stockholders' equity	$ 19,928	$ 20,892

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	$ 1,651	$ 517	$ 4,077	$ 1,529
General and administrative	1,848	2,448	5,406	9,487
Total operating expenses	3,499	2,965	9,483	11,016
Loss from operations	(3,499)	(2,965)	(9,483)	(11,016)
Other income (expense), net	3	(5)	(8)	10
Net loss and comprehensive loss	$ (3,496)	$ (2,970)	$ (9,491)	$ (11,006)
Net loss per share, basic and diluted	$ (0.37)	$ (0.43)	$ (1.07)	$ (2.25)
Weighted-average common shares outstanding, basic and diluted	9,420,039	6,943,058	8,864,895	3,845,258