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 14, 2019
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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	NVUS	Nasdaq Capital Market

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 14, 2019, Novus Therapeutics, Inc. (the "Company") announced its financial results for the period ended March 31, 2019. 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 14, 2019

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 14, 2019

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

Exhibit 99.1

Novus Therapeutics Reports First Quarter 2019 Financial Results

May 14, 2019 at 4:05 PM Eastern Daylight 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 March 31, 2019.

Operational Highlights

- Announced results of two single-dose OP0201 phase 1 clinical trials, demonstrating safety and tolerability in healthy adults (study C-001) and in adults with acute otitis media (study C-004)
- Completed enrollment of multi-dose OP0201 phase 1 clinical trial in healthy adults (study C-002, three doses daily for 14-days), with results expected next month
- Initiated enrollment of multi-dose OP0201 exploratory phase 2a clinical trial in infants and children with acute otitis media (study C-006, two doses daily for 10-days)

“We had a very productive first quarter with the completion of two single-dose safety and tolerability OP0201 clinical trials,” said Gregory J. Flesher, CEO of Novus Therapeutics. “In addition, we completed enrollment of our 14-day safety and tolerability study in healthy adults and expect to report results next month.”

“In February we announced the initiation of our first phase 2 study, an exploratory phase 2a clinical trial designed to explore the effects of a 10-day course of OP0201 treatment in combination with oral antibiotics in infants and children with acute otitis media. With the recently completed $10.7 million financing, we plan to expand enrollment of this study from 50 to approximately 140 patients and now expect to report results in the first half of 2020,” concluded Mr. Flesher.

Financial Results for First Quarter 2019

For the three-months ended March 31, 2019, Novus reported a net loss of $4.9 million, or $0.52 per share, compared to a net loss of $2.8 million, or $0.36 per share, for the same period in 2018. The company had $9.1 million in cash and cash equivalents as of March 31, 2019.

R&D expenses were $3.0 million during the three-months ended March 31, 2019, compared to $1.1 million for the same period in 2018. We expect R&D expenses to increase in subsequent periods as we advance our OP0201 program.

G&A expenses were $1.9 million during the three-months ended March 31, 2019, compared to $1.7 million for the same period in 2018.

Upcoming Milestones

- June 2019 – Results of OP0201 phase 1 study C-002
- June 2019 – Poster presentation of OP0201 phase 1 study C-001 data at the 20th International Symposium on Recent Advances in Otitis Media (June 9-13, Los Angeles, CA)
- 1H 2020 – Results of OP0201 phase 2a study C-006

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). The Company has two platform technologies, each with the potential to be developed for multiple indications. Novus' lead program (OP0201) is a surfactant-based nasal aerosol drug-device combination product candidate being developed as a potential first-in-class treatment option for patients at risk for, or with, otitis media (OM), which is middle ear inflammation and effusion with or without infection. Globally, OM affects more than 700 million adults and children every year, with over half of the cases occurring in children under five years of age. OM is one of the most common disorders seen in pediatric practice, and in the U.S. 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 platform (OP01xx), 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," "looks forward," "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: risks related to market conditions, the completion of the common stock and warrant financing, including the satisfaction of the closing conditions, and the use of anticipated proceeds; expectations regarding the timing for the commencement and completion of product development or clinical trials, including the four ongoing OP0201 clinical trials; expectations regarding the success of 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 quarterly, annual, and other filings with the SEC, which can be found at www.sec.gov. 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.
Source: Novus Therapeutics, Inc.

Investor Contacts

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

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash	$ 9,056	$ 12,972
Prepaid expenses and other current assets	1,265	1,304
Total current assets	10,321	14,276
Property and equipment, net	12	14
Operating lease asset, net	446	—
Goodwill	1,867	1,867
Other assets	805	869
Total assets	$ 13,451	$ 17,026
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 480	$ 689
Current operating lease liability	170	—
Accrued expenses and other liabilities	2,591	1,845
Total current liabilities	3,241	2,534
Non-current operating lease liability	281	—
Total liabilities	3,522	2,534
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2019 and December 31, 2018; 9,447,361 and 9,422,143 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	9	9
Additional paid-in capital	56,372	56,054
Accumulated deficit	(46,452)	(41,571)
Total stockholders' equity	9,929	14,492
Total liabilities and stockholders' equity	$ 13,451	$ 17,026

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

	For the Three Months Ended March 31,	
	2019	2018
Operating expenses		
Research and development	$ 2,989	$ 1,097
General and administrative	1,886	1,698
Total operating expenses	4,875	2,795
Loss from operations	(4,875)	(2,795)
Other income (expense), net	(6)	(11)
Net loss and comprehensive loss	$ (4,881)	$ (2,806)
Net loss per share, basic and diluted	$ (0.52)	$ (0.36)
Weighted-average common shares outstanding, basic and diluted	9,427,073	7,749,263