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 15, 2020
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 15, 2020, Novus Therapeutics, Inc. (the "Company") announced its financial results for the period ended March 31, 2020. 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 15, 2020

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 15, 2020

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

Novus Therapeutics Reports First Quarter 2020 Financial Results

May 15, 2020 at 6:30 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, today announced financial results for the quarter ended March 31, 2020.

Operational Highlights

- Raised gross proceeds of approximately $5.8 million through the exercise of outstanding warrants in January 2020
- Completed enrollment of OP0201 phase 2a clinical trial in acute otitis media (study C-006) in March 2020

Upcoming Milestones

- Topline results of OP0201 phase 2a clinical trial in acute otitis media (study C-006) are expected in early June 2020

“During the quarter, we accomplished two key objectives of extending our cash runway and completing enrollment of study C-006, our exploratory phase 2a clinical trial of OP0201 in infants and children with acute otitis media,” said Gregory J. Flesher, CEO of Novus Therapeutics, Inc. “We now have cash through year-end 2020 and all patients have subsequently completed the trial. We look forward to sharing the topline result of study C-006 in the coming weeks,” concluded Mr. Flesher.

Financial Results for the Three Months Ended March 31, 2020

The company reported a net loss of $8.2 million, or $0.47 per share, for the three months ended March 31, 2020, compared to a net loss of $4.9 million, or $0.52 per share, for the same period in 2019. The company had $11.8 million in cash and cash equivalents as of March 31, 2020.

Research and development (R&D) expenses were $1.6 million for the three months ended March 31, 2020, compared to $3.0 million for the same period in 2019. The decrease in R&D expenses were primarily attributed to reductions of $806,000 in clinical, $706,000 in CMC, $46,000 in travel and meeting expenses, and $3,000 in miscellaneous operating costs. The decrease was partially offset by increases of $17,000 in personnel costs, $85,000 in consulting costs, and $118,000 in stock-based compensation.

General and administrative (G&A) expenses were $1.7 million for the three months ended March 31, 2020, compared to $1.9 million for the same period in 2019. The decrease in G&A expenses were primarily attributed to reductions of $257,000 in public company costs, $107,000 in litigation costs, $20,000 in general operating costs, and $15,000 in travel and meeting expenses. The decrease was partially offset by increases of $136,000 in personnel costs and $107,000 in stock-based compensation.

During the quarter, the Company recognized a non-operating non-cash warrant inducement expense of $4.8 million.

About Study C-006

Study C-006 is a phase 2a, single center, double-blind, randomized, placebo-controlled, parallel group clinical trial to assess the safety, tolerability, and efficacy of 20 mg per day intranasal OP0201 as an adjunct therapy to oral antibiotic in the treatment of acute otitis media in infants and children aged 6 to 24 months. Subjects were treated twice-daily for 10 days and followed for up to 20 additional days after treatment has been completed (up to 30-days in total). The study was designed to detect a 25% treatment effect over placebo in at least one of the two primary efficacy endpoints. The primary efficacy endpoints include resolution of bulging tympanic membrane 4-6 days after initiation of treatment (visit 2) and resolution of middle ear effusion 12-14 days after initiation of treatment (visit 3). Please see clinicaltrials.gov for additional information (identifier NCT03818815).

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. 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 ongoing OP0201 clinical trial; 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 10-Q, annual 10-K, 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, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash	$ 11,785	$ 8,791
Prepaid expenses and other current assets	1,088	1,180
Total current assets	12,873	9,971
Property and equipment, net	3	5
Operating lease asset, net	272	316
Other assets	572	639
Total assets	$ 13,720	$ 10,931
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 741	$ 329
Current operating lease liability	184	180
Accrued expenses and other liabilities	953	813
Total current liabilities	1,878	1,322
Non-current operating lease liability	97	144
Total liabilities	1,975	1,466
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized at March 31, 2020 and December 31, 2019; 3,796 and 0 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2020 and December 31, 2019; 16,069,562 and 12,967,338 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	16	13
Additional paid-in capital	77,488	67,034
Accumulated deficit	(65,759)	(57,582)
Total stockholders' equity	11,745	9,465
Total liabilities and stockholders' equity	$ 13,720	$ 10,931

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

	For the Three Months Ended March 31,	
	2020	2019
Operating expenses		
Research and development	$ 1,648	$ 2,989
General and administrative	1,730	1,886
Total operating expenses	3,378	4,875
Loss from operations	(3,378)	(4,875)
Other income (expense), net	30	(6)
Warrant inducement expense	(4,829)	—
Net loss and comprehensive loss	$ (8,177)	$ (4,881)
Net loss per share, basic and diluted	$ (0.47)	$ (0.52)
Weighted-average common shares outstanding, basic and diluted	17,267,123	9,427,073