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

March 17, 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 March 17, 2020, Novus Therapeutics, Inc. (the "Company") announced its financial results for the period ended December 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 March 17, 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: March 17, 2020

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

EXHIBIT 99.1

Novus Therapeutics Reports Fourth Quarter and Full-Year 2019 Financial Results

Data from the fully enrolled phase 2a efficacy study in infants and children with acute otitis media to be announced by early June 2020

March 17, 2020 at 7:30 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 fourth quarter and full-year ended December 31, 2019.

“We made steady progress in the OP0201 development program during 2019. During the year, the company generated data from three phase 1 safety studies, which established safety and tolerability of single and multiple doses of OP0201 in both healthy adult volunteers and in adults with acute otitis media. We also initiated our first phase 2a efficacy study in patients with acute otitis media. Finally, we completed a successful meeting with the U.S. FDA in which we gained alignment on study design and endpoints for a phase 2 study in patients with chronic otitis media with effusion, ” said Gregory J. Flesher, CEO of Novus Therapeutics.

“Looking ahead, we expect to announce data from the fully enrolled phase 2a efficacy study in infants and children with acute otitis media in the coming months,” concluded Mr. Flesher.

Financial Results for the Three Months Ended December 31, 2019

The company reported a net loss of $4.1 million, or $0.32 per share, for the three months ended December 31, 2019, compared to a net loss of $4.6 million, or $0.49 per share, for the same period in 2018.

Research and development (R&D) expenses were $1.3 million for the three months ended December 31, 2019, compared to $2.7 million for the same period in 2018. The decrease in R&D expenses of $1.4 million is primarily attributed to a decrease of clinical and formulation development costs for OP0201 of $612,000 and $432,000, respectively, as well as savings in personnel costs of $431,000, stock-based compensation of $59,000, and travel and meetings expense of $36,000. The decreases were partially offset by an increase in consulting services of $163,000.

General and administrative (G&A) expenses were $1.0 million for the three months ended December 31, 2019, compared to $1.8 million for the same period in 2018. The decrease in G&A expenses of $870,000

is primarily attributed to a decrease of $556,000 in personnel costs, $439,000 in stock-based compensation, and costs associated with operating a publicly traded company of $141,000. The decreases were partially offset by an increase in litigation costs of $266,000.

Financial Results for the Year Ended December 31, 2019

Novus reported a net loss of $16.0 million, or $1.36 per share, for the year ended December 31, 2019, compared to a net loss of $14.1 million, or $1.56 per share, for the same period in 2018.

R&D expenses were $8.1 million for the year ended December 31, 2019, compared to $6.8 million for the same period in 2018. The increase in R&D expenses of $1.3 million for the year ended December 31, 2019 was primarily due to an increase in clinical development costs of $1.8 million and an increase in consulting costs of $131,000 related to the advancement of our OP0201 programs, as well as an increase in stock-based compensation of $94,000. The increases were offset by a decrease in formulation and device development costs of $474,000, and decreases in personnel and travel related costs of $163,000 and $112,000, respectively. As we advance our clinical development programs, R&D expenses are expected to increase.

G&A expenses were $6.1 million for the year ended December 31, 2019, compared to $7.2 million for the same period in 2018. The decrease in G&A expenses of $1.2 million for the year ended December 31, 2019 was primarily due to a reduction of $590,000 in administrative costs associated with operating a public company, as well as decreases in personnel costs and stock-based compensation of $163,000 and $330,000, respectively. Additionally, general operating costs decreased $87,000 and travel related expenses decreased $21,000. The decreases were offset by an increase in litigation costs of $4,000.

The company had approximately $8.8 million in cash and cash equivalents as of December 31, 2019, compared to approximately $10.8 million in cash and cash equivalents as of September 30, 2019.

In January 2020, the company received gross proceeds of approximately $5.8 million through the exercise of warrants that were issued in a private placement in May 2019. The company’s cash and cash equivalents, including the cash received from warrants, is expected to fund operations through year end 2020.

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,791	$ 12,972
Prepaid expenses and other current assets	1,180	1,304
Total current assets	9,971	14,276
Property and equipment, net	5	14
Operating lease asset, net	316	—
Goodwill	—	1,867
Other assets	639	869
Total assets	$ 10,931	$ 17,026
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable	$ 329	$ 689
Current operating lease liability	180	—
Accrued expenses and other liabilities	813	1,845
Total current liabilities	1,322	2,534
Non-current operating lease liability	144	—
Total liabilities	1,466	2,534
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2019 and 2018; 12,967,338 and 9,422,143 shares issued and outstanding at December 31, 2019 and 2018, respectively	13	9
Additional paid-in capital	67,034	56,054
Accumulated deficit	(57,582)	(41,571)
Total stockholders' equity	9,465	14,492
Total liabilities and stockholders' equity	$ 10,931	$ 17,026

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

	Year Ended December 31,	
	2019	2018
Operating expenses		
Research and development	$ 8,128	$ 6,817
General and administrative	6,056	7,243
Goodwill impairment	1,867	—
Total operating expenses	16,051	14,060
Loss from operations	(16,051)	(14,060)
Other income (expense), net	40	(5)
Net loss and other comprehensive loss	$ (16,011)	$ (14,065)
Net loss per share, basic and diluted	$ (1.36)	$ (1.56)
Weighted-average common shares outstanding, basic and diluted	11,793,125	9,005,352