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, 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 November 13, 2019, Novus Therapeutics, Inc. (the "Company") announced its financial results for the period ended September 30, 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 November 13, 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: November 13, 2019

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

Novus Therapeutics Reports Third Quarter 2019 Financial Results

-- Management to participate in two investor conferences in December 2019 --

-- Data from ongoing phase 2a study C-006 expected in the first half of 2020 --

November 13, 2019 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 (ENT), today announced financial results for the quarter ended September 30, 2019.

“We continue to make progress with the OP0201 otitis media program,” said Gregory J. Flesher, CEO of Novus Therapeutics, Inc. “To date we have enrolled more than 40% of the planned patients into study C-006, our ongoing phase 2a clinical trial in infants and children with acute otitis media. Study C-006 is designed to explore the effect of OP0201 in resolving a bulging tympanic membrane and/or resolving middle ear effusion, both of which are hallmark symptoms of acute otitis media. We expect results from this study to be available in the first half of 2020.”

“In addition, we recently had a meeting with the FDA in which we gained alignment on the overall design and efficacy endpoints for study C-009, our planned phase 2a clinical trial in infants and children with chronic otitis media with effusion. This non-infectious form of otitis media affects millions of people every year and is characterized by middle ear effusion and hearing loss that persists for many months. Study C-009 is designed to explore the effect of OP0201 in restoring hearing and/or resolving middle ear effusion in patients with bilateral chronic otitis media with effusion. We look forward to initiating this study in the future,” concluded Mr. Flesher.

Upcoming Milestones

- Results of OP0201 phase 2a study in acute otitis media (study C-006) in the first half of 2020

Upcoming Investor Conferences

- Piper Jaffray Healthcare Conference, Lotte Palace Hotel, New York, December 3-5, 2019
- LD Micro Conference, Luxe Sunset Hotel, Los Angeles, CA December 10-12, 2019

Financial Results for the Three Months Ended September 30, 2019

The company reported a net loss of $2.9 million, or $0.22 per share, for the three months ended September

30, 2019, compared to a net loss of $3.5 million, or $0.37 per share, for the same period in 2018.

Research and development (R&D) expenses were $1.5 million for the three months ended September 30, 2019, compared to $1.7 million for the same period in 2018. The decrease in R&D expenses of $142,000 is primarily due to lower clinical and formulation development costs, as well as a decrease in travel and meetings expense. The decreases were offset by an increase in consulting services, personnel costs, and stock-based compensation costs.

General and administrative (G&A) expenses were $1.4 million for the three months ended September 30, 2019, compared to $1.8 million for the same period in 2018. The decrease in G&A expenses of $437,000 is primarily attributable to a decrease in litigation costs, costs associated with operating a publicly traded company, stock-based compensation costs, and general operating costs. The decreases were offset by increases in personnel costs and travel and meetings expense.

Financial Results for the Nine Months Ended September 30, 2019

Novus reported a net loss of $11.9 million, or $1.04 per share, for the nine months ended September 30, 2019, compared to a net loss of $9.5 million, or $1.07 per share, for the same period in 2018.

R&D expenses were $6.8 million for the nine months ended September 30, 2019, compared to $4.1 million for the same period in 2018. The increase in R&D expenses of $2.7 million is primarily attributable to an increase in clinical development costs for OP0201, personnel costs, stock-based compensation, and an increase in other development costs. The increases were offset by decreases in formulation development costs and travel and meetings expense.

G&A expenses were $5.1 million for the nine months ended September 30, 2019, compared to $5.4 million for the same period in 2018. The decrease in G&A expenses of $317,000 was primarily due to decreases in costs associated with operating a publicly traded company, litigation costs, general operating costs, as well as a decrease in travel and meetings expense. The decreases were offset by increases in personnel and stock-based compensation costs.

The company had approximately $10.8 million in cash and cash equivalents as of September 30, 2019, compared to approximately $13.7 million in cash and cash equivalents as of June 30, 2019. The company’s cash and cash equivalents is expected to fund operations through study C-006 data in 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 (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 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)

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash	$ 10,814	$ 12,972
Prepaid expenses and other current assets	1,482	1,304
Total current assets	12,296	14,276
Property and equipment, net	7	14
Operating lease asset, net	360	—
Goodwill	1,867	1,867
Other assets	688	869
Total assets	$ 15,218	$ 17,026
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 256	$ 689
Current operating lease liability	177	—
Accrued expenses and other liabilities	1,228	1,845
Total current liabilities	1,661	2,534
Non-current operating lease liability	191	—
Total liabilities	1,852	2,534
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 12,974,923 and 9,422,143 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	13	9
Additional paid-in capital	66,791	56,054
Accumulated deficit	(53,438)	(41,571)
Total stockholders' equity	13,366	14,492
Total liabilities and stockholders' equity	$ 15,218	$ 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 September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 1,509	$ 1,651	$ 6,795	$ 4,077
General and administrative	1,411	1,848	5,089	5,406
Total operating expenses	2,920	3,499	11,884	9,483
Loss from operations	(2,920)	(3,499)	(11,884)	(9,483)
Other income (expense), net	27	3	17	(8)
Net loss and comprehensive loss	$ (2,893)	$ (3,496)	$ (11,867)	$ (9,491)
Net loss per share, basic and diluted	$ (0.22)	$ (0.37)	$ (1.04)	$ (1.07)
Weighted-average common shares outstanding, basic and diluted	12,974,923	9,420,039	11,397,364	8,864,895