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

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

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

Novus Therapeutics Reports Second Quarter 2019 Financial Results

August 13, 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 June 30, 2019.

Operational Highlights

- Announced results from three OP0201 phase 1 safety clinical trials
- Presented OP0201 data at the 20th International Symposium on Recent Advances in Otitis Media
- Raised gross proceeds of $10.7 million in a registered direct offering

“During the quarter, we completed the OP0201 phase 1 program which included a single-dose safety trial in healthy adults (study C-001), a single-dose safety trial in adults with acute otitis media (study C-004), and a 14-day safety trial in healthy adults (study C-002),” said Gregory J. Flesher, CEO of Novus Therapeutics, Inc.

“The phase 1 program has shown OP0201 to be safe and tolerable, and we are now focusing our R&D activities towards the ongoing exploratory phase 2a trial in children with acute otitis media (study C-006). To date, we have enrolled more than 30% of the planned 140 patients into study C-006 and we look forward to sharing the results of this study in the first half of 2020. Finally, we are continuing to advance our plans for the phase 2 trial in children with chronic otitis media with effusion (study C-009) and plan to meet with the FDA in September to discuss the program,” concluded Mr. Flesher.

Financial Results for Second Quarter 2019

For the three-months ended June 30, 2019, the company reported a net loss of $4.1 million, or $0.35 per share, compared to a net loss of $3.2 million, or $0.34 per share, for the same period in 2018. For the six-months ended June 30, 2019, Novus reported a net loss of $9.0 million, or $0.85 per share, compared to a net loss of $6.0 million, or $0.70 per share, for the same period in 2018. The company had $13.7 million in cash as of June 30, 2019.

Research and development (R&D) expenses were $2.3 million for the three-months ended June 30, 2019, compared to $1.3 million for the same period in 2018. The increase in R&D expenses for the three month period was primarily due to an increase in clinical related costs for OP0201 of $924,000, as well as increases in stock-based compensation expense of $141,000, consulting services of $45,000, and personnel costs of

$44,000. The increases were partially offset by a decrease in formulation development costs for OP0201 of $132,000 and travel and meeting expense of $54,000. For the six-months ended June 30, 2019, R&D expenses were $5.3 million, compared to $2.4 million for the same period in 2018. The increase in R&D expenses for the six month period was primarily due to an increase in clinical related costs for OP0201 of $2.5 million, an increase in personnel costs of $234,000, an increase in stock-based compensation of $147,000, and an increase in formulation development costs for OP0201 of $134,000. The increases were partially offset by a decrease in consulting costs of $127,000 as more work was performed in-house and a decrease and travel and meetings expense of $55,000. We expect research and development expenses to increase in subsequent periods as we advance our OP0201 program.

General and administrative (G&A) expenses were $1.8 million for the three-months ended June 30, 2019, compared to $1.9 million for the same period in 2018. The decrease in G&A expenses for the three month period was primarily due to a decrease in litigation costs of $154,000, costs associated with operating a publicly traded company of $83,000, and travel and meeting expense of $37,000. This decrease was partially offset by an increase in personnel costs of $125,000 and $81,000 in stock-based compensation costs. For the six-months ended June 30, 2019, G&A expenses were $3.7 million, compared to $3.6 million for the same period in 2018. The increase in G&A expenses for the six month period was primarily due to an increase in personnel costs of $282,000 and an increase in stock-based compensation of $126,000. These increases were partially offset by a decrease of $205,000 in costs associated with operating a publicly traded company, $45,000 in litigation costs and $38,000 in other G&A costs. We expect quarterly recurring G&A expenses to remain flat for the remainder of calendar 2019.

Upcoming Milestones

- September 2019 – FDA meeting to discuss OP0201 phase 2 study in children with chronic otitis media with effusion (study C-009)
- 1H 2020 – Results of OP0201 phase 2a study in children with acute otitis media (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)

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash	$ 13,703	$ 12,972
Prepaid expenses and other current assets	1,478	1,304
Total current assets	15,181	14,276
Property and equipment, net	10	14
Operating lease asset, net	403	—
Goodwill	1,867	1,867
Other assets	755	869
Total assets	$ 18,216	$ 17,026
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 753	$ 689
Current operating lease liability	173	—
Accrued expenses and other liabilities	1,022	1,845
Total current liabilities	1,948	2,534
Non-current operating lease liability	236	—
Total liabilities	2,184	2,534
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and none issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2019 and December 31, 2018; 12,974,923 and 9,422,143 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	13	9
Additional paid-in capital	66,564	56,054
Accumulated deficit	(50,545)	(41,571)
Total stockholders' equity	16,032	14,492
Total liabilities and stockholders' equity	$ 18,216	$ 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 June 30,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 2,297	$ 1,329	$ 5,286	$ 2,426
General and administrative	1,792	1,860	3,678	3,558
Total operating expenses	4,089	3,189	8,964	5,984
Loss from operations	(4,089)	(3,189)	(8,964)	(5,984)
Other income (expense), net	(4)	—	(10)	(11)
Net loss and comprehensive loss	$ (4,093)	$ (3,189)	$ (8,974)	$ (5,995)
Net loss per share, basic and diluted	$ (0.35)	$ (0.34)	$ (0.85)	$ (0.70)
Weighted-average common shares outstanding, basic and diluted	11,751,110	9,407,024	10,595,511	8,582,723