

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 8, 2017
Date of Report
(Date of earliest event reported)

Novus Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36620
(Commission
File Number)

20-1000967
(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)

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 8, 2017, Novus Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2017. 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 8, 2017](#)

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 8, 2017

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

Novus Therapeutics Reports Third Quarter 2017 Results

IRVINE, Calif., Nov. 8, 2017 /PRNewswire/ -- Novus Therapeutics, Inc. (NASDAQ: NVUS), a development stage specialty pharmaceutical company focused on the development of products for disorders of the ear, nose, and throat (ENT), announced financial results for the quarter ended September 30, 2017.

For the third quarter of 2017, Novus reported a net loss of \$3.0 million, or \$0.43 loss per share, compared to a net loss of \$2.0 million, or \$4.35 loss per share, for the same period in 2016. For the nine months ended September 30, 2017, Novus reported a net loss of \$11.0 million, or \$2.25 loss per share, as compared to a net loss of \$4.1 million, or \$9.09 loss per share, for the first nine months of 2016. Novus ended the third quarter 2017 with \$19.1 million in cash and cash equivalents.

Research and development (R&D) expenses were \$517,000 during the third quarter of 2017 compared to \$1.1 million for the same period in 2016. For the nine months ended September 30, 2017, R&D expenses were \$1.5 million, compared to \$2.3 million for the same period in 2016. The decrease in R&D expense for both periods is primarily due to decreased spending towards the OP-01 program, offset by wind-down costs incurred for legacy Tokai programs. We expect R&D expenses to increase in subsequent periods as we advance our OP-02 program.

General and administrative (G&A) expenses were \$2.5 million for the third quarter of 2017 compared to \$0.6 million for the third quarter of 2016. For the nine months ended September 30, 2017, G&A expenses were \$9.5 million, compared to \$1.3 million for the first nine months of 2016. The increase in G&A expense for both periods is primarily due to merger related expenses of \$7.2M, plus legal costs associated with the legacy Tokai litigation and administrative costs associated with operating as a publicly traded company.

"We are continuing formulation development and clinical planning activities for our OP-02 program and we are expecting to begin our clinical trials in 2018," said Gregory J. Flesher, Chief Executive Officer of Novus Therapeutics. "As a potential first-in-class treatment option to both treat and prevent otitis media, OP-02 has the ability to dramatically improve the lives of millions of patients around the world."

About Novus Therapeutics

Novus Therapeutics is a development stage specialty pharmaceutical company focused on the development of products for disorders of the ear, nose, and throat (ENT). Novus has two technologies, each of which has the potential to be developed for multiple ENT indications. The company's lead product (OP-02) is a surfactant-based, combination drug product being developed as a potential first-in-class treatment option for patients at risk for or with otitis media ("OM") (middle ear inflammation and effusion with or without infection). Globally, OM affects more than 700 million adults and children every year. OM is a common disorder seen in pediatric practice, and in the United States is the most frequent reason children are prescribed antibiotics and undergo surgery. Novus also has a foam-based drug delivery technology (OP-01), 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

Exhibit 99.1

Any statements in this press release about the company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, the review of strategic alternatives and the outcome of such review and other statements containing the words "believes," "anticipates," "plans," "expects," "may," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, expectations regarding the timing for the commencement and completion of our clinical trials and our ability to accelerate the development of our drug candidates. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the sufficiency of the company's cash resources; the ability to timely develop and manufacture clinical batches of our study drugs; the ability to obtain necessary 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, 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, it will be successfully distributed and marketed. 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.

Investor Contacts

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Exhibit 99.1

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

	September 30, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,094	\$ 1,103
Restricted cash	—	14
Prepaid expenses and other current assets	1,941	33
Total current assets	21,035	1,150
Property and equipment, net	47	31
Restricted cash	70	—
Goodwill	1,867	—
Other assets	—	15
Total assets	<u>\$ 23,019</u>	<u>\$ 1,196</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 189	\$ 338
Accrued severance	963	—
Accrued expenses and other liabilities	1,154	113
Convertible notes	—	3,447
Total current liabilities	2,306	3,898
Long-term liabilities	94	—
Total liabilities	2,400	3,898
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized and none issued and outstanding at September 30, 2017; preferred stock, \$0.0026 par value, 6,565,540 shares authorized and 452,706 shares issued and outstanding at December 31, 2016	—	11
Common stock, \$0.001 par value, 200,000,000 shares authorized and 6,943,058 shares issued and outstanding at September 30, 2017; common stock, \$0.0026 par value, 9,207,060 shares authorized and 82,246 shares issued and outstanding at December 31, 2016	7	1
Additional paid-in capital	46,008	11,385
Receipts on account of Preferred A stock	—	291
Accumulated deficit	(25,396)	(14,390)
Total stockholders' equity (deficit)	20,619	(2,702)
Total liabilities and stockholders' equity (deficit)	<u>\$ 23,019</u>	<u>\$ 1,196</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses				
Research and development	\$ 517	\$ 1,053	\$ 1,529	\$ 2,335
General and administrative	2,448	564	9,487	1,326
Total operating expenses	2,965	1,617	11,016	3,661
Loss from operations	(2,965)	(1,617)	(11,016)	(3,661)
Other income (expense), net	(5)	(418)	10	(479)
Net loss and comprehensive loss	\$ (2,970)	\$ (2,035)	\$ (11,006)	\$ (4,140)
Net loss per share, basic and diluted	\$ (0.43)	\$ (4.35)	\$ (2.25)	\$ (9.09)
Weighted-average common shares outstanding, basic and diluted	6,943,058	81,339	3,845,258	79,026

NOVUS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2017	2016
Operating activities		
Net loss	\$ (11,006)	\$ (4,140)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18	16
Stock-based compensation	386	142
Loss on disposal of fixed assets	31	—
Fair value of debt in excess of proceeds	—	517
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(761)	42
Accounts payable and accrued expenses	(998)	(218)
Net cash used in operating activities	(12,330)	(3,641)
Investing activities		
Cash received from merger transaction	23,250	—
Proceeds from sale of equipment	8	—
Purchase of property and equipment	—	(12)
Net cash provided by (used in) investing activities	23,258	(12)
Financing activities		
Proceeds from issuance of common stock, net	4,000	—
Proceeds from exercise of warrants	3,119	—
Proceeds from convertible loan	—	2,930
Net cash provided by financing activities	7,119	2,930
Net increase (decrease) in cash, cash equivalents and restricted cash	18,047	(723)
Cash, cash equivalents and restricted cash at beginning of period	1,117	3,095
Cash, cash equivalents and restricted cash at end of period	\$ 19,164	\$ 2,372
Supplemental disclosure of cash flow information		
Noncash activities:		
Conversion of promissory notes and interest to common stock	\$ 3,447	\$ —
Conversion of contingently issuable shares to common stock	\$ 291	\$ —
Fair value of assets acquired and liabilities assumed in the merger:		
Fair value of assets acquired, excluding cash and restricted cash	\$ 3,072	
Fair value of liabilities assumed	(2,947)	
Fair value of net assets acquired in the merger	\$ 125	