
**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 9, 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.)

**1990 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 August 9, 2017, Novus Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended June 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 August 9, 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: August 10, 2017

By: /s/ Gregory J. Flesher

Name: Gregory J. Flesher

Title: Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Novus Therapeutics, Inc., dated August 9, 2017

Novus Therapeutics Reports Second Quarter 2017 Results

IRVINE, Calif., August 9, 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), today reported results for the second quarter 2017.

For the three months ended June 30, 2017, Novus reported a net loss of \$6.7 million or \$1.32 per share. This compares to a net loss of \$1.0 million or \$2.25 per share for the same period in the prior year. For the six months ended June 30, 2017, Novus reported a net loss of \$8.0 million or \$2.51 per share. This compares to a net loss of \$2.1 million or \$4.68 per share for the same period in the prior year. Novus ended the second quarter of 2017 with \$22.5 million in cash and cash equivalents.

“The second quarter was a transformational period for the company,” said Gregory J. Flesher, President and Chief Executive Officer. “We completed the previously announced merger with Tokai Pharmaceuticals, Inc., made changes to the leadership team, consolidated operations to our Irvine headquarters, and embarked on a focused effort to advance OP-02 as a potential first-in-class treatment option for the millions of patients burdened by otitis media.”

Recent Business Highlights and Corporate Update

- **Completion of the Merger:** On May 9, 2017, the previously announced merger between Otic Pharma, Ltd. and Tokai Pharmaceuticals, Inc. was completed and the name of the combined company was changed to Novus Therapeutics, Inc. On May 11, 2017, Novus began trading on the NASDAQ Capital Market under the ticker symbol “NVUS.”
- **Financing Activities:** Novus raised an additional \$7.1 million in gross proceeds in connection with the merger. The proceeds included \$4.0 million obtained through a private placement of the company’s common stock on May 10, 2017 and approximately \$3.1 million obtained through the exercise of Otic Pharma, Ltd. warrants prior to close of the merger.
- **Leadership Change:** Jon Kuwahara joined Novus as Senior Vice President of Finance and Administration, succeeding Christine Ocampo. Mr. Kuwahara has over 25 years of finance and operations experience, primarily within the pharmaceutical industry. Mr. Kuwahara is a member of the Board of Directors, and Chairman of the Audit Committee, for Emmaus Life Sciences, Inc. and has held past finance roles at Espero Pharmaceuticals, Avanir Pharmaceuticals, and Questcor Pharmaceuticals.
- **Research and Development:** Given the current capital resources, Novus made the strategic decision to focus substantially all of its development activities to the advancement of OP-02 for otitis media, an opportunity management believes has the greatest potential to create significant shareholder value. Novus is currently conducting formulation development activities on OP-02, and upon successful completion and manufacturing of clinical supply, plans to begin human studies in 2018. Novus currently maintains nine prostate cancer patients in a safety study of galeterone, but has terminated all other research and development activities related to galeterone.

Financial Results for the Three Months and Six Months Ended June 30, 2017

Research and development expenses for the three-month and six-month periods ended June 30, 2017 decreased to approximately \$0.5 million and \$1.0 million, as compared to \$0.6 million and \$1.3 million respectively, for the same periods in 2016. The change was primarily attributed to decreased spending towards OP-01 and offset by costs incurred for Tokai's legacy development programs during 2017.

General and administrative expenses for the three-month and six-month periods ended June 30, 2017 increased to approximately \$6.1 million and \$7.0 million, as compared to \$0.3 million and \$0.8 million, respectively for the same periods in 2016. The change was primarily attributed to \$5.4 million in one-time merger related expenses for the three-month period ended June 30, 2017 and public company related expenses, including severance costs for previous Tokai employees.

About Novus Therapeutics

Novus Therapeutics is a development stage 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 with or without infection), which is often caused by Eustachian tube dysfunction ("ETD"). 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 for delivery of drugs into the ear, nose, and sinus cavities. For more information on Novus, please visit novustherapeutics.com.

Forward-looking Statements

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

	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 22,498	\$ 1,103
Restricted cash	13	14
Prepaid expenses and other current assets	<u>2,332</u>	<u>33</u>
Total current assets	24,843	1,150
Property and equipment, net	49	31
Restricted cash	70	—
Goodwill	1,867	—
Other assets	15	15
Total assets	<u>\$ 26,844</u>	<u>\$ 1,196</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 374	\$ 338
Accrued severance	1,300	—
Accrued expenses and other liabilities	1,486	113
Convertible notes	<u>—</u>	<u>3,447</u>
Total current liabilities	3,160	3,898
Long-term liabilities	<u>245</u>	<u>—</u>
Total liabilities	3,405	3,898
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 and 452,706 shares issued and outstanding at June 30, 2017 and December 31, 2016	—	11
Common stock, \$0.001 par value, 200,000,000 shares authorized; 6,943,832 and 82,246 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	7	1
Additional paid-in capital	45,858	11,385
Goodwill	—	291
Accumulated deficit	<u>(22,426)</u>	<u>(14,390)</u>
Total stockholders' equity (deficit)	<u>23,439</u>	<u>(2,702)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 26,844</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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Operating expenses				
Research and development	\$ 533	\$ 592	\$ 1,012	\$ 1,282
General and administrative	6,133	340	7,039	762
Total operating expenses	<u>6,666</u>	<u>932</u>	<u>8,051</u>	<u>2,044</u>
Loss from operations	(6,666)	(932)	(8,051)	(2,044)
Other income (loss), net	4	(70)	15	(61)
Net loss and comprehensive loss	<u>\$ (6,662)</u>	<u>\$ (1,002)</u>	<u>\$ (8,036)</u>	<u>\$ (2,105)</u>
Net loss per share, basic and diluted	<u>\$ (1.32)</u>	<u>\$ (2.25)</u>	<u>\$ (2.51)</u>	<u>\$ (4.68)</u>
Weighted-average shares outstanding, basic and diluted	<u>4,154,842</u>	<u>77,856</u>	<u>2,270,907</u>	<u>77,856</u>

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

	Six Months Ended June 30,	
	2017	2016
Operating activities		
Net loss	\$ (8,036)	\$(2,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	16	20
Stock-based compensation	236	85
Loss on disposal of fixed assets	31	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,167)	45
Accounts payable and accrued expenses	7	(207)
Net cash used in operating activities	(8,913)	(2,162)
Investing activities		
Cash received from merger transaction	23,250	—
Proceeds from sale of equipment	8	—
Purchase of property and equipment	—	(10)
Net cash provided by (used in) investing activities	23,258	(10)
Financing activities		
Proceeds from issuance of common stock, net	4,000	—
Proceeds from exercise of warrants	3,119	—
Net cash provided by financing activities	7,119	—
Net increase (decrease) in cash, cash equivalents and restricted cash	21,464	(2,172)
Cash, cash equivalents and restricted cash at beginning of period	1,117	3,109
Cash, cash equivalents and restricted cash at end of period	<u>\$22,581</u>	<u>\$ 937</u>
Supplemental disclosure of cash flow information		
Noncash activities:		
Conversion of promissory notes and interest to common stock	<u>\$ 3,447</u>	<u>\$ —</u>
Conversion of preferred stock to common stock	<u>\$ 9</u>	<u>\$ —</u>
Conversion of contingently issuable shares to common stock	<u>\$ 291</u>	<u>\$ —</u>
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	<u>\$ 125</u>	