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

April 22, 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)

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 8.01 Other Events.

On April 22, 2019, Novus Therapeutics, Inc. issued a press release announcing the results of two single-dose phase 1 clinical studies with OP0201. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release, dated April 22, 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: April 22, 2019

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

Novus Therapeutics Announces Results of Two Single-Dose Phase 1 Studies of OP0201

OP0201 Was Safe and Well-Tolerated in Healthy Adults and Adults with Acute Otitis Media

April 22, 2019 at 8:00 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 results from two single-dose phase 1 clinical trials of OP0201. The primary objective of establishing safety and tolerability was achieved in both healthy adults (study C-001) and in adults with acute otitis media (study C-004).

"We are delighted that results from the OP0201 single-dose phase 1 clinical trials met the primary objectives and demonstrated a favorable safety and tolerability profile," said Dr. Catherine Turkel, President of Novus
Therapeutics, "The safety profile was similar between OP0201 and placebo, and similar between healthy adults and adults with acute otitis media. Study participants did not report any adverse effect on smell or taste after exposure to OP0201 in either study. In study C-001, we did not observe any adverse effect on Eustachian tube function. In study C-004, the majority of the participants in both treatment groups reported relief of ear pain, although no treatment difference was observed between the groups."

Study C-001 was a randomized, double-blind, cross-over, single-dose phase 1 trial in healthy adults designed to evaluate safety, tolerability, and explore Eustachian tube function within a 150-minute period following a single 20 mg intranasal dose of OP0201 or placebo while participants were exposed to changes in pressure induced by a 6-minute hyperbaric/hypobaric protocol in an atmospheric pressure chamber.

- The mean age of the 17 participants was 25.8 years, 52.9% were female
- In total, 76.5% (13/17) of participants who received OP0201 and 81.3% (13/16) of participants who received placebo experienced one or more adverse events
- The most common OP0201 adverse events occurring in more than 2 participants and greater than placebo were tympanic membrane hyperemia and tympanic membrane disorder. These events were attributed by the ENT physician investigator to be related to the pressure chamber and not deemed related to OP0201 or placebo
- No serious adverse events occurred during the study

Study C-004 was a randomized, double-blind, placebo-controlled, parallel-group phase 1 trial in adults with acute otitis media and moderate or worse ear pain designed to evaluate safety, tolerability, and explore relief of ear pain within a 60-minute period following a single 20 mg intranasal dose of OP0201 or placebo.

- The mean age of the 24 participants was 49.5 years, 66.7% were female
- In total, 16.7% (2/12) of participants who received OP0201 and 50.0% (6/12) of participants who received placebo experienced one or more adverse events. The two adverse events reported in the two participants who received OP0201 were mild nasal discomfort and mild lacrimation increase. Both

adverse events were mild and resolved
- No serious adverse events occurred during the study

“We have also recently completed our multiple-dose phase 1 safety trial, and in the coming months we will report data from the 14-day, dose-escalation safety and tolerability study in healthy adults. Further, this past February we initiated our phase 2a pediatric otitis media development program which is ongoing, and by year end we will have our first look at safety, tolerability and efficacy with 10 days of OP0201 treatment compared to placebo in infants and children with acute otitis media,” concluded Dr. Turkel.

Study C-002 is a phase 1 clinical trial designed to evaluate safety and tolerability of twice daily intranasal administration of OP0201 over 14 consecutive days in 30 healthy adults. The randomized, double-blind, placebo- controlled, parallel-group, dose-escalation trial includes a 30 mg per day dose (Cohort A) and 60 mg per day dose (Cohort B) of OP0201.

Study C-006 is an exploratory phase 2a clinical trial designed to evaluate safety, tolerability, and efficacy of twice daily intranasal administration of OP0201 over 10 consecutive days in infants and children 6 to 24 months of age with acute otitis media. The randomized, double-blind, placebo-controlled, parallel-group trial explores the effects of a 20 mg per day dose of OP0201 as an adjunct to oral antibiotics. Patients will be followed for up to 30 days, during which multiple efficacy endpoints will be explored.

About OP0201

OP0201 is being developed as a potential first-in-class treatment option for OM. OM is often caused by Eustachian tube dysfunction (ETD). OP0201 is a nasal aerosol, drug-device combination product comprised of a novel formulation of a surfactant (dipalmitoylphosphatidylcholine [DPPC]) and a spreading agent (cholesteryl palmitate [CP]) suspended in propellant. The product is administered intranasally via a pressurized metered-dose inhaler (pMDI). OP0201 is intended to be used to restore the normal physiologic activity of the ET, which is a small tube that connects the middle ear cavity to the back of the nasopharynx. Together, the active ingredients in OP0201 effectively absorb to the air-liquid interface of the mucosa and reduce the interfacial surface tension of the ET, which reduces passive pressure required for the ET to open. In other words, OP0201 is intended to promote ‘de- sticking’ of the ET so that ventilation of the middle ear may occur.

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: 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.

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