

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 29, 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 November 29, 2017, Novus Therapeutics, Inc. (the "Company") posted an investor presentation to its website at <http://ir.novustherapeutics.com/events-and-presentations/presentations>. A copy of the investor presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

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 [Novus Therapeutics, Inc., Investor Presentation dated November 29, 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 29, 2017

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



Corporate Presentation

November 29, 2017



Forward-Looking Statements

This presentation 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, the review of strategic alternatives and the outcome of such review and other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "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; 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 annual report on Form 10-K for the year ended December 2016, as well as our subsequent filings with the SEC which can be found at www.sec.gov. Any forward-looking statements contained in this presentation 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.



Key Takeaways

- Two platform technologies (OP-01 and OP-02) that can be developed for multiple ear and nasal/sinus indications
- Potential to create significant value with a transformational, first-in-class treatment option for otitis media (OP-02)
- Otitis media has significant unmet clinical need (no drug products approved to treat or prevent otitis media)



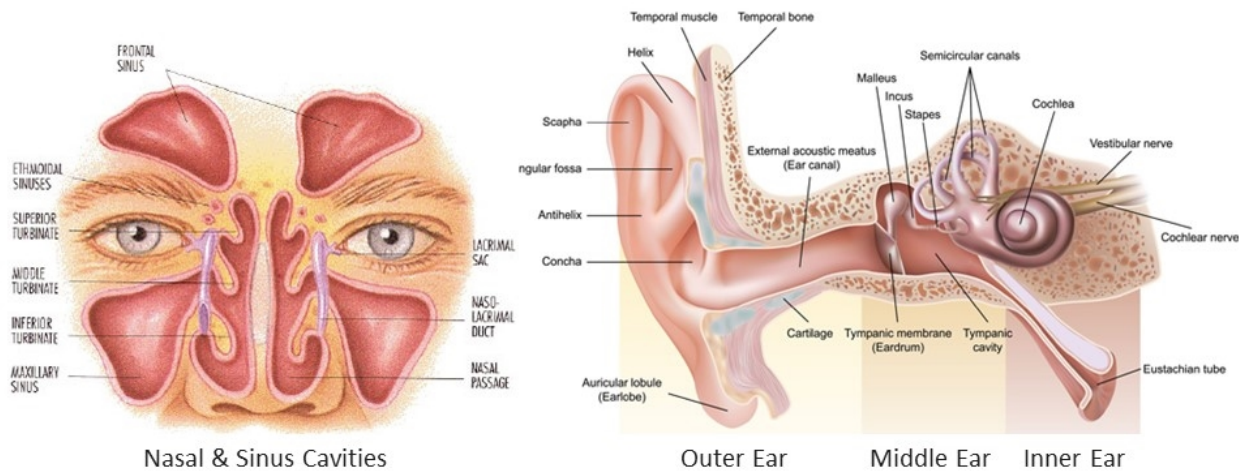
Novus Therapeutics

- Development stage specialty pharmaceutical company
- Focusing on the development of a novel drug product for management of otitis media, a middle ear disease
- NASDAQ-listed company as of May 2017 (“NVUS”)
- Reported \$19.1 million cash at September 30, 2017
- Experienced management team with a proven track record of developing novel drugs and creating shareholder value





Product Opportunities





Otitis Media

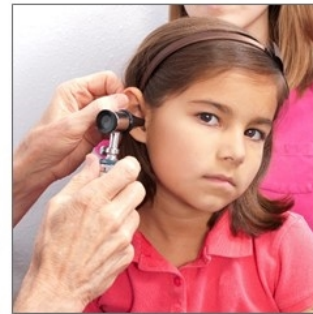
"Otitis media (OM) is the most common disease seen in pediatric practice, a leading cause of health care visits, and the most frequent reason children consume antibiotics or undergo surgery..."

Marom et al, JAMA Pediatrics 2014;168(1):68-75



Overview of Otitis Media

- Otitis media (OM) is an umbrella term that encompasses a spectrum of inflammatory diseases of the middle ear
 - *Acute otitis media (AOM)*
 - *Otitis media with effusion (OME)*
 - *Chronic suppurative otitis media (CSOM)*
- AOM symptoms commonly include sudden onset of earache and fever; OME symptoms include a sensation of “fullness” in the ears and hearing impairment
 - *Complications may include behavioral changes, speech/learning issues, perforation of eardrums, permanent hearing loss, and other morbidities*
- Global incidence of 700+ million cases annually with over half occurring in children under five years old¹
 - *80% will have ≥ 1 episodes by age 3*
 - *40% will have ≥ 6 episodes by age 7*



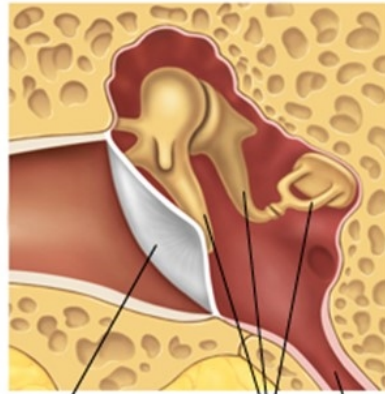
1. Monasta et al, PLoSONE 2012;7:e36226



Pathophysiology of Otitis Media

OM occurs due to inflammation of the nasopharynx and Eustachian tube (bacterial/viral infections, allergies, etc.)

Normal Middle Ear



Eardrum

Auditory bones

Eustachian tube

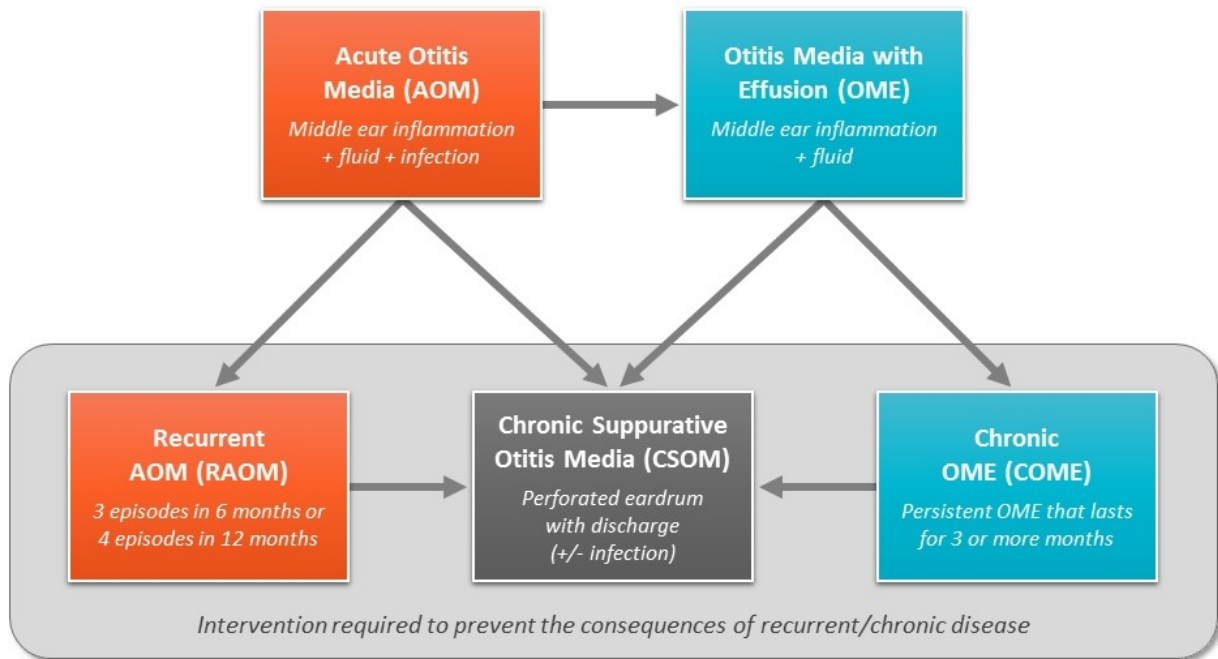
Otitis Media



Middle ear fluid



Continuum of Otitis Media





Management of Otitis Media



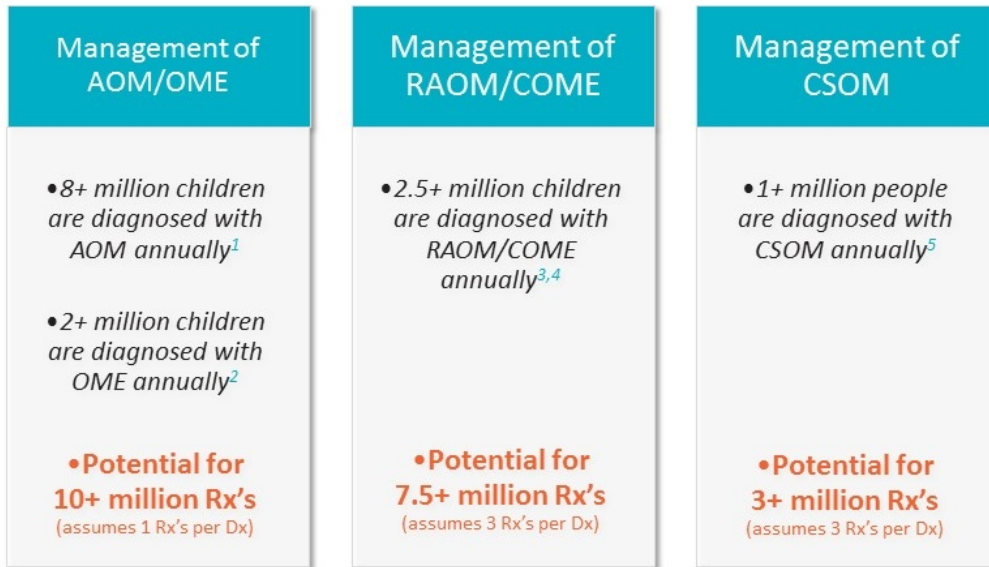
AAO-HNS = American Academy Otolaryngology Head & Neck Surgery; AAP = American Academy of Pediatrics; AAFP = American Academy Family Practice

- \$5+ billion spent annually on management in the U.S.¹
- Antibiotics are frequently prescribed (over-prescribed)
 - *AAO-HNS, AAP, and AAFP guidelines recommend against use in OME²*
 - *Cannot prevent recurrent episodes of AOM/OME*
- Surgery to insert ventilation tubes into the eardrum has become standard of care
 - *1 million surgeries performed annually in the U.S.³*

1. Casey et al, Clin Pediatr (Phila) 2014;53:865-873
2. Rosenfeld et al, Otolaryngol Head Neck Surg 2016;154(1S):S1-S41
3. Kesser et al, Surgery of Ventilation and Mucosal Disease 2010;(6):73-91



U.S. Market Opportunity



1. Ahmed et al, Laryngoscope 2014;124:301-305
2. Rosenfeld et al, Otolaryngol Head Neck Surg 2016;154(1S):S1-S41
3. Lous et al, Int J Pediatr Otorhinolaryngol 2011;75:1058-1061
4. Rosenfeld et al, Otolaryngol Head Neck Surg 2016;154(1S):S1-S41
5. Monasta et al, PLoSONE 2012;7:e36226



Surfactant Program (OP-02)



Overview of OP-02

- Novel drug-device product being developed as first-in-class treatment option for otitis media
- Proprietary formulation of two surfactant active ingredients
 - *Dipalmitoylphosphatidylcholine (DPPC)*
 - *Cholesteryl palmitate (CP)*
- Daily use nasal spray designed to help restore and maintain Eustachian tube (ET) function
 - *Lowers ET surface tension and promotes “de-sticking”*
- Proof of concept successfully demonstrated in multiple animal species, plus supportive anecdotal evidence in humans

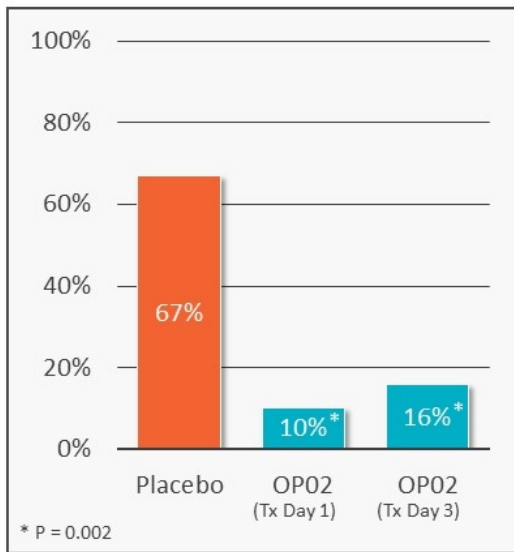


OP-02 Preclinical Studies

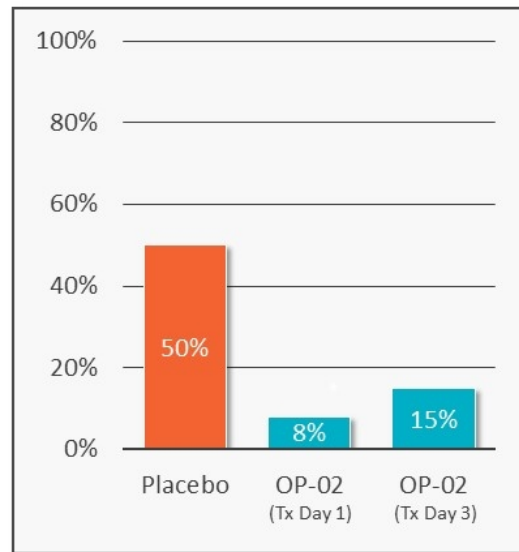
Study	Description	Animals	Result
1	Administration of OP-02 in a metered dose aerosolized intranasal delivery system to <i>healthy animals</i> ¹	Gerbils + Mice	<i>Reduction of Eustachian tube passive opening pressure within minutes of administration</i>
2	Administration of OP-02 in a metered dose aerosolized intranasal delivery system to <i>animals with OME</i> ²	Gerbils	<i>Reduction in both the severity and duration of OME</i>
3	Administration of OP-02 in a metered dose aerosolized intranasal delivery system to <i>animals with AOM</i> ³	Chinchillas	<i>Reduction in both the severity and duration of AOM</i>

1. Chandrasekhar et al, Otolology and Neurotology 2002;23:3-7
2. Venkatayan et al, Otolaryngology Head Neck Surgery 2001;124:388-93
3. Chandrasekhar et al, Laryngoscope 2004;114:472-85

Middle Ears with Infection (Day 27)



Inner Ears with Inflammation (Day 8)





OP-02 Human Experience

- Prior to acquiring rights to the surfactant program, the inventors treated 9 human patients with various OM/ETD conditions
 - *Ages ranged from 4 – 75 years old*
 - *Used for both treatment and as a prophylaxis*
 - *Some subjects used the product repeatedly over years*
- The human experience was captured as case studies and reported to the FDA (also used for a new patent application)
- Case studies were consistent with the preclinical animal data



Case Study #4

Adult with Rhinitis and Left Clogged Eustachian Tube



*Treatment
with OP-02*



Time 0:

++erythema, boggy wet mucosa and copious thin mucus with a noticeable absence of bubbles at Eustachian tube orifice

Time 10 min:

Patient begins to feel clearing of the ear and is able to open the Eustachian tube on sustained yawns

Time 15 min:

Patient reports that ear has opened up; bubbles begin to form at the Eustachian tube orifice (air exchange)



Next Steps for OP-02 Program

- Formulation and device development ongoing
- Phase 1 studies planned:
 - *Safety/tolerability of daily use (2 weeks treatment)*
 - *Pharmacodynamic effect on Eustachian tube function*
- Phase 2 studies planned:
 - *Treatment of AOM and prevention of OME in children*
 - *Prevention of AOM and OME in “otitis prone” children*



Otitis Externa



Overview of Acute Otitis Externa



- Common condition of the external ear canal involving inflammation and infection
- Causes include trapped moisture, trauma, poor cleanliness, and chronic dermatologic conditions
- Symptoms include ear pain, itching, edema, reddening of the skin, and ear discharge
- 6.7 million anti-infective prescriptions written for the ear annually in the U.S.¹
 - *CIPRODEX® (ciprofloxacin/dexamethasone) represents one-third of anti-infective class*
 - 4 drops per ear, twice-daily for 7-days
 - Median time to end of pain = 5 days

1. IQVIA (IMS Health) NSP and NPA data for calendar 2015
2. CIPRODEX is a registered trademark of Bayer AG, licensed to Alcon by Bayer AG

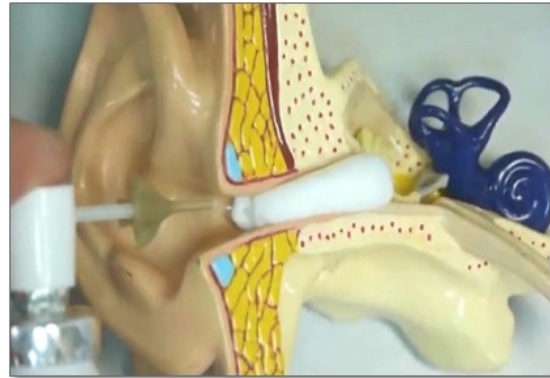


Foam Program (OP-01)



Overview of OP-01

- Aerosol foam formulation designed to be used as a drug delivery vehicle
- Antibiotic-only product successfully validated through phase 2 for acute otitis externa
 - *Non-inferior to CIPRODEX using 50% fewer doses over 7-days (7 doses versus 14 doses)*
- Combination drug product (antibiotic + anesthetic) being considered as a clinically differentiated treatment option for acute otitis externa patients
 - *Rapid relief of ear pain (an unmet need)*
 - *Treatment duration less than 7-days*





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- Otitis media has significant unmet clinical need (no drug products approved to treat or prevent otitis media)



Thank You

NASDAQ: NVUS
novustherapeutics.com
