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

January 7, 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 7.01 Regulation FD Discosure

On January 7, 2019, Novus Therapeutics, Inc. (the "Company") posted an investor presentation to its website. 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 7.01 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 Investor Presentation, dated January 7, 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: January 8, 2019

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

Exhibit 99.1

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, 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 quarterly report on Form 10-Q for the quarter ended September 30, 2018, as well as other 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.

Corporate Profile

Two platform technologies
Clinical-stage specialty pharmaceutical company with two platform technologies (OP01xx and OP02xx)

Large market opportunity
Global incidence of 700+ million cases annually

First-in-class treatment
Lead asset is a novel, surfactant-based intranasal drug product being developed for otitis media

Experienced management team
Track record of successfully developing products and creating value (Avanir, Allergan, Questcor, etc.)

Unmet clinical need
No approved drugs products for treatment of otitis media or prevention of recurrent/chronic otitis media

Clinical milestones
Four OP0201 clinical trials planned for 2019, including three clinical trials that will explore efficacy


Otitis Media

1. Monasta et al, PLoS ONE 2012;7:e38226
2. Tong et al. BMC Health Services Research (2018) 18:318

Overview of Otitis Media

Otitis media (OM) is an umbrella term that encompasses a spectrum of inflammatory diseases of the middle ear

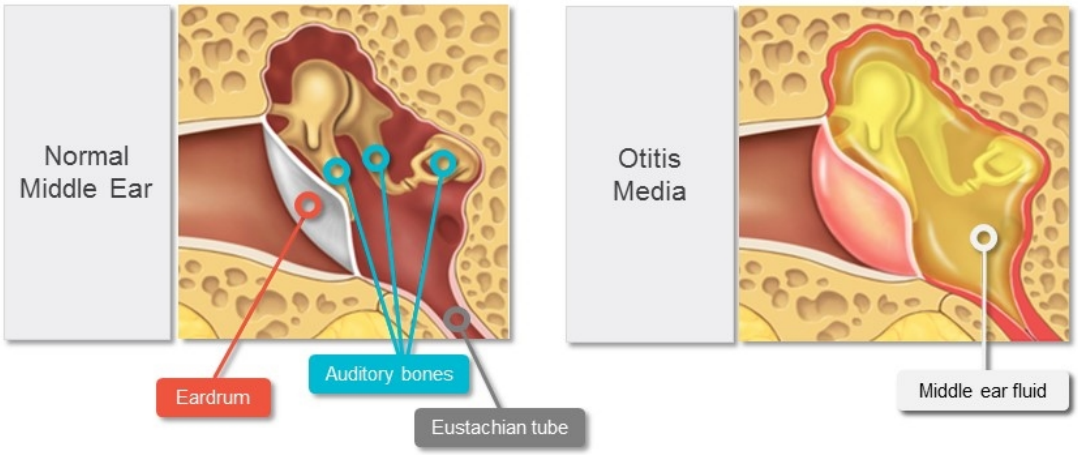
- Acute otitis media or "AOM" is middle ear inflammation and effusion with signs and symptoms of infection (bulging eardrum, pain, etc.)
  - ❖ Recurrent AOM or "RAOM" is defined as 3 or more AOM episodes in 6-months or 4 or more episodes in 12-months
- Otitis media with effusion or "OME" is middle ear inflammation and effusion without signs and symptoms of infection
  - ❖ Chronic OME or "COME" is defined as 3 or more months of persistent OME

Global incidence of 700+ million cases annually with over half occurring in children under five years old[1]

- 40% of children will have 6 or more episodes by age 7
- More than 15 million physician office visits annually in the U.S.[2]

Pathophysiology of Otitis Media (OM)

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



Current Management of Otitis Media

$5+ Billion

Spent annually on management in the U.S. alone[1]

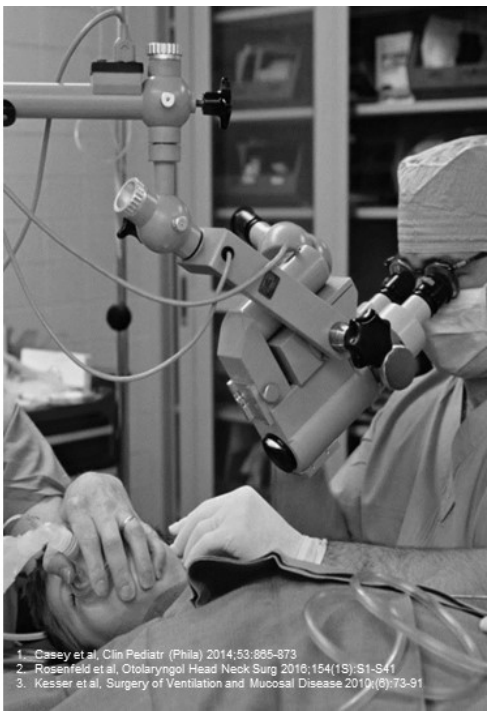
Antibiotics are frequently prescribed (over-prescribed)

Antibiotics do not treat OME or prevent recurrent episodes of AOM (RAOM)

AAO-HNS, AAP, and AAFP guidelines recommend against antibiotics in OME[2]

Surgery to insert ventilation tubes into the eardrum has become the 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 Research (Management of Otitis Media)

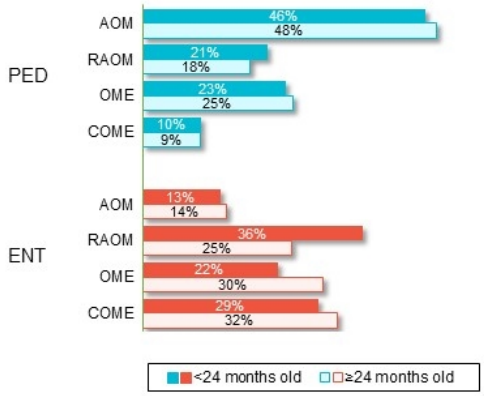
Novus conducted quantitative market research with 50 Pediatricians ("PED") and 30 Otolaryngologists ("ENT") to better understand the current management of otitis media and the potential utilization of OP0201 for otitis media

PED/ENTs manage a large number of OM patients

PED	Average	Median	Range
Monthly OM Patients	156	90	35-600
Age of OM Patients (years)	3	3	0-25

ENT (61% pediatric)	Average	Median	Range
Monthly OM Patients	93	40	15-600
Age of OM Patients (years)	17	10	0-98

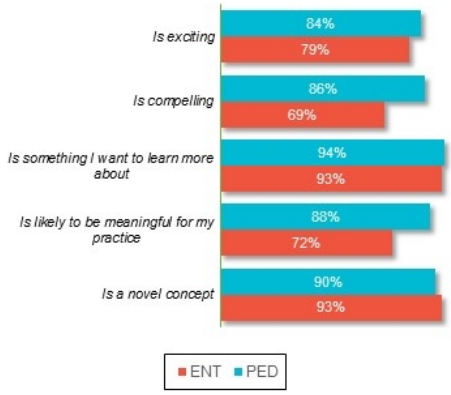
ENTs manage a greater amount of chronic/recurrent OM



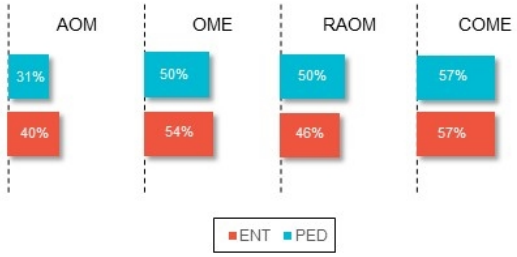
Novus Quantitative Market Research May 2018 (data on file)

U.S. Market Research (Impression and Stated Utilization of OP0201)

PED/ENTs are favorable to the OP0201 product profile
(agree/strongly agree to the following statements)



PED/ENTs intend to utilize OP0201 across all OM types



Novus Quantitative Market Research May 2018 (data on file)


Surfactant Program (OP0201)

Overview of Surfactant Program (OP0201)

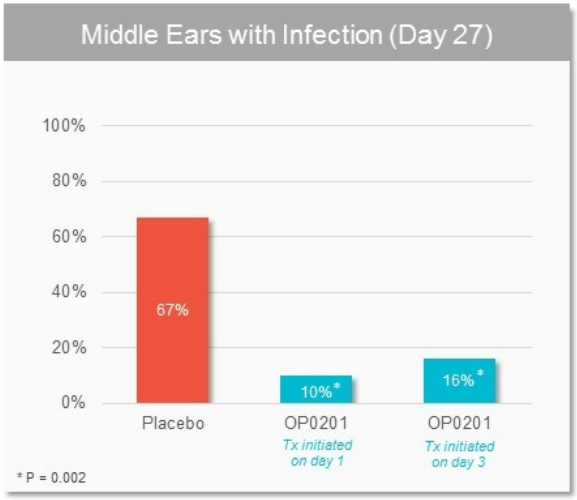
- Novel drug-device product being developed as a first-in-class treatment option for otitis media
- Proprietary formulation of two active ingredients
  - *Dipalmitoylphosphatidylcholine (DPPC)*
  - *Cholesteryl palmitate (CP)*
- Daily use nasal spray designed to help restore and maintain Eustachian tube (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
- Phase 1 program ongoing (includes trials with exploration of efficacy)

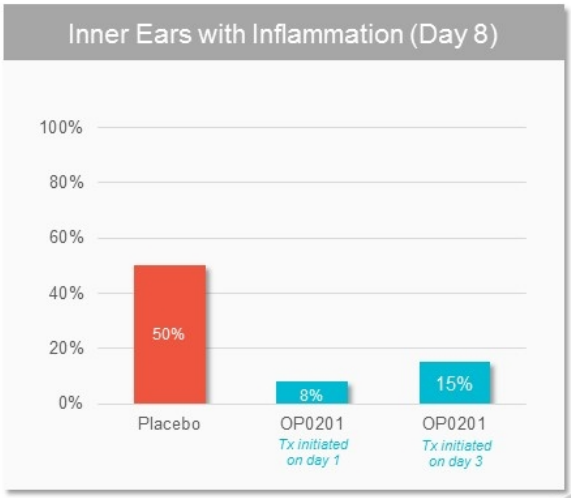
OP0201Preclinical Studies

Study	Description	Animals	Result
1	Administration of OP0201 in a metered dose aerosolized intranasal delivery system to healthy animals[1]	Gerbils + Mice	Reduction of Eustachian tube passive opening pressure within minutes of administration
2	Administration of OP0201 in a metered dose aerosolized intranasal delivery system to animals with OME[2]	Gerbils	Reduction in both the severity and duration of OME
3	Administration of OP0201 in a metered dose aerosolized intranasal delivery system to animals with AOM[3]	Chinchillas	Reduction in both the severity and duration of AOM

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

Chinchillas with AOM (Study #3)





1. Chandrasekhar and Mautone, Laryngoscope 2004;114:472-85

OP0201 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 prevention
- Some subjects used the product over many years
- Captured as case studies and reported to the FDA (also used in a patent application)
- Experience was consistent with the animal data

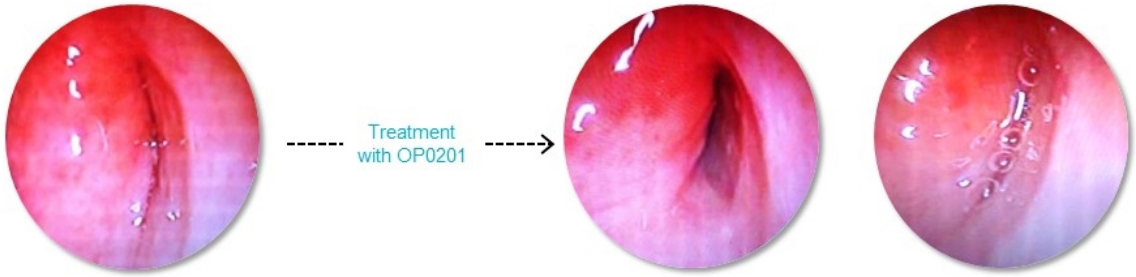
Novus is currently conducting a 14-day safety/tolerability study in health adults subjects (2 cohorts of 15 subjects each)

- First cohort (30 mg/day) completed with no severe or serious adverse events
- Second cohort (60 mg/day) currently recruiting

OM = otitis media; ETD = Eustachian tube dysfunction

OP0201 Human Experience (Case Study #4)

Endoscopic observation of an adult male with rhinitis and left clogged Eustachian tube



Time 0	Time 10 min	Time 15 min
++erythema, boggy wet mucosa and copious thin mucus with a noticeable absence of bubbles at Eustachian tube orifice	Patient begins to feel clearing of the ear and is able to open the Eustachian tube on sustained yawns	Patient reports that ear has opened up; bubbles begin to form at the Eustachian tube orifice (air exchange)

Ongoing OP0201 Clinical Trials

Study OP0201-C-002
ClinicalTrials.gov: NCT03748758

- Safety/tolerability in 30 healthy adults
- Randomized, double-blind, placebo-controlled, parallel-group, dose-escalation design
- 14-days treatment with either 30 mg/day OP0201 or placebo (4:1) and 60 mg/day OP0201 or placebo (4:1)
- Topline data expected Q1 2019

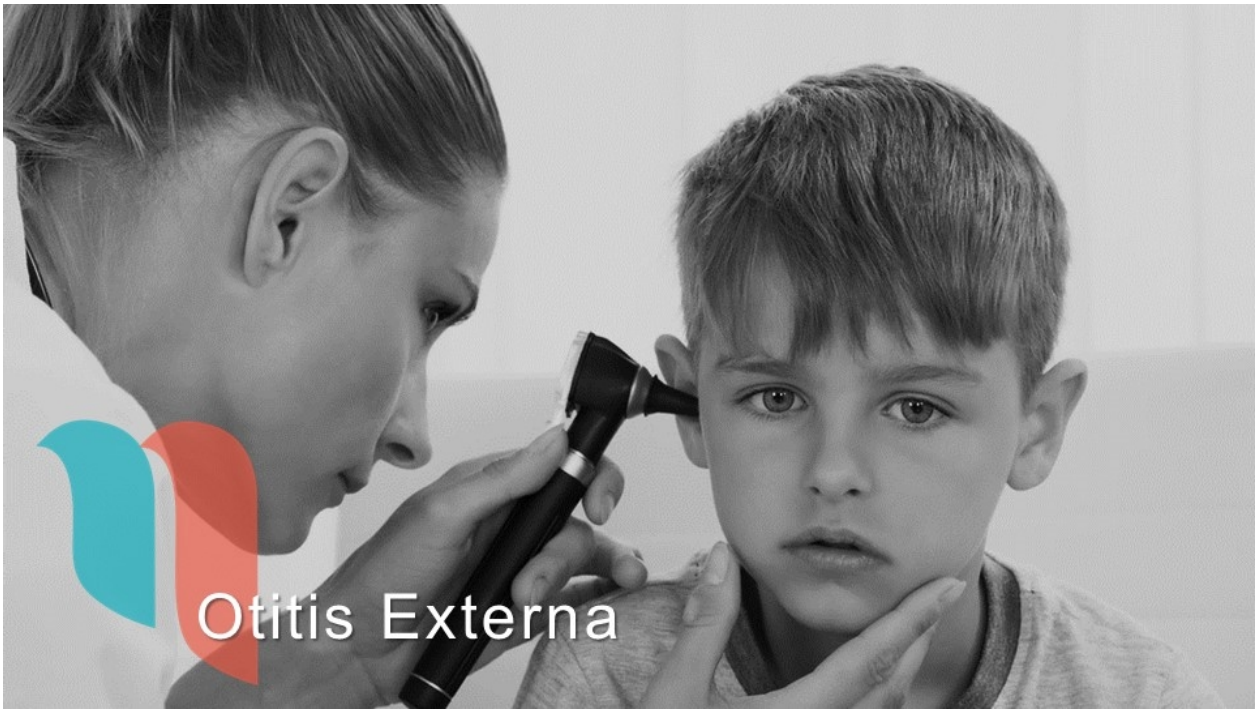
Study OP0201-C-004
ClinicalTrials.gov: NCT03766373

- Safety and exploration of efficacy in up to 24 adults with AOM (relief of ear pain)
- Randomized, double-blind, placebo-controlled, parallel-group design
- 1 hour observation following a single 20 mg dose of OP0201 or placebo (1:1)
- Pain relief will be captured utilizing pain scales and patient/clinician global assessments of change scales

Additional OP0201 Clinical Trials

- Planned clinical studies for 1H 2019 (data in 2019)
  - *Phase 1 safety and exploration of efficacy in children with OME (resolution of middle ear effusion)*
  - *Phase 1 safety and pharmacodynamic effects in adults (effect on Eustachian tube function)*

- Planned clinical studies for 2H 2019 (data in 2020+)
  - *Phase 2 safety and efficacy in children with AOM (treat AOM + prevent subsequent AOM/OME)*
  - *Phase 2 safety and efficacy in children with COME (treat OME + restore hearing)*


Otitis Externa

Overview of Acute Otitis Externa

Inflammation and Infection

Common condition of the external ear canal involving inflammation and infection

Symptoms

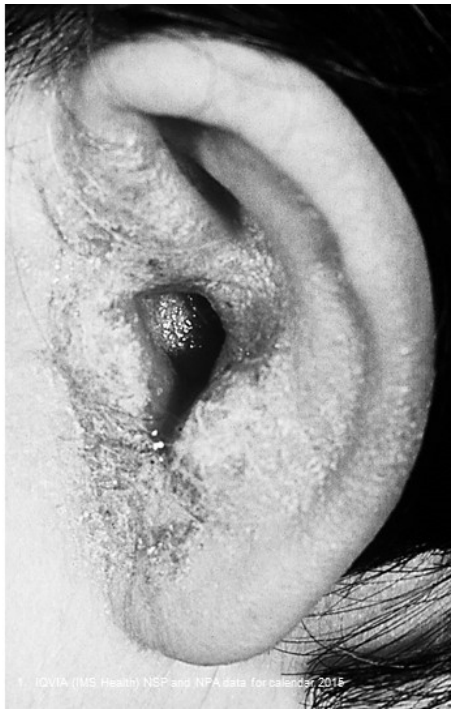
Symptoms include ear pain, itching, edema, reddening of the skin, and ear discharge

Chronic dermatologic conditions

Causes include trapped moisture, trauma, poor cleanliness, and chronic dermatologic conditions

Antibiotic prescriptions

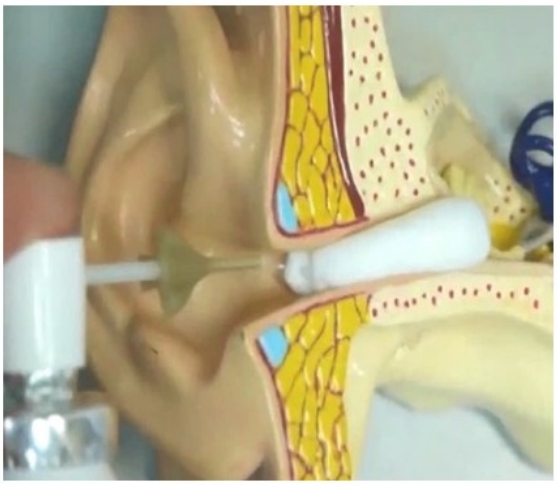
6.7 million antibiotic prescriptions written for the ear annually in the U.S.[1]



1. IQVIA (IMS Health) NSP and NPA data for calendar 2018


Foam Program (OP0102)

Overview of Antibiotic Ear Foam



Novus developed an novel aerosol foam to be used as a drug delivery vehicle (ears, nose/sinus)

Completed successful phase 2 clinical trial in AOE with a first-generation, antibiotic-only foam product (OP0101)

- *Non-inferior to CIPRODEX® using 50% fewer doses*

Completed initial formulation work on second-generation combination drug product (OP0102) intended to be a clinically differentiated treatment option for AOE

- *Addition of anesthetic for rapid pain relief (unmet need)*
- *Shorter treatment duration (less than 7-days)*

AOE = acute otitis externa
CIPRODEX is a registered trademark of Bayer AG, licensed to Alcon by Bayer AG

Intellectual Property

Surfactant Patents and Applications

7 U.S. and 3 foreign patents (last to expire issued patent in the U.S. in Nov 2019

1 U.S. patent application, 1 International (PCT) patent application, and 2 foreign patent application (methods of use with expiration 2036+)

1 provisional patent application claiming novel drug substance and pharmaceutical compositions (composition of matter with expiration 2039+)

Foam Patents and Applications

3 U.S. and 7 foreign patents (last to expire issued patent in the U.S. in Sep 2027)

2 U.S. patent applications, 1 of which has recently been allowed, and 3 foreign patent applications (allowed U.S. application will expire in Dec 2033, absent any adjustments)