Novus | Investor Presentation

NASDAQ: NVUS

NOVUS therapeutics

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-K 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 surfactant (OP02xx) and foam (OP01xx) technologies

Large market opportunity

Global incidence of 700+ million otitis media cases annually, affecting both children and adults

First-in-class treatment

OP0201 is a novel, surfactant-based drug-device product being developed for otitis media

Experienced management team

Track record of successfully developing products and creating value (Allergan, Avanir, Intermune, Questcor)

Unmet clinical need

No approved drug products for treatment of otitis media or prevention of recurrent/chronic otitis media

Multiple clinical milestones

Four OP0201 clinical trials in calendar 2019, including three phase 1 studies and one phase 2a study


Otitis Media

Overview of Otitis Media

Global incidence of 700+ million cases of OM annually[1]

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

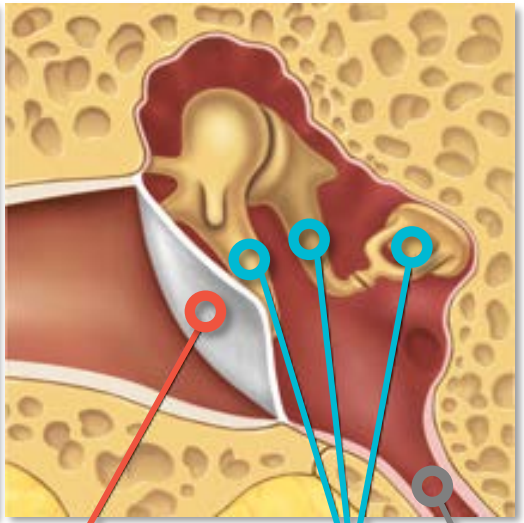
Otitis media (OM) is an umbrella term that encompasses a spectrum of inflammatory diseases of the middle ear

- Acute otitis media or "AOM" is middle ear inflammation and effusion with signs and symptoms of infection (bulging eardrum, pain, etc.)
  - *≥3 AOM episodes within 6-months or ≥4 AOM episodes within 12-months is recurrent AOM or "RAOM"*
- Otitis media with effusion or "OME" is middle ear inflammation and effusion without signs and symptoms of infection
  - *≥3 months of OME is chronic OME or "COME"*

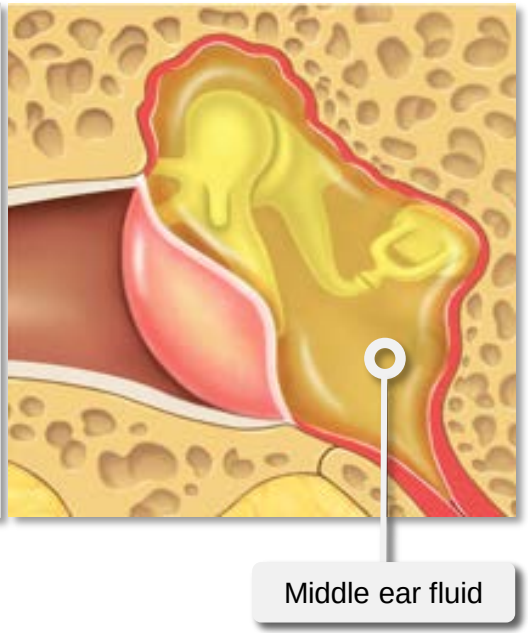
1. Monasta et al, PLoS ONE 2012;7:e36226
2. Tong et al. BMC Health Services Research (2018) 18:318

Pathophysiology of Otitis Media

Normal Middle Ear



Otitis Media



Current Management of Otitis Media

$5+ Billion

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

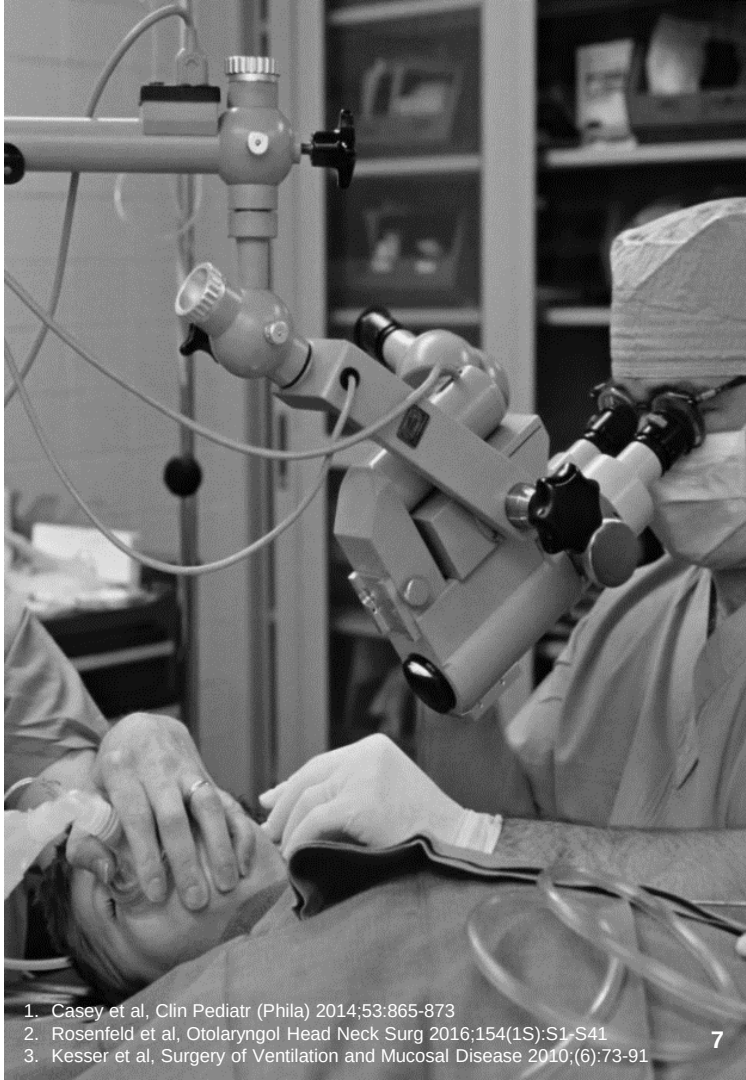
Antibiotics are frequently prescribed (over-prescribed)

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

Physician Management of Otitis Media

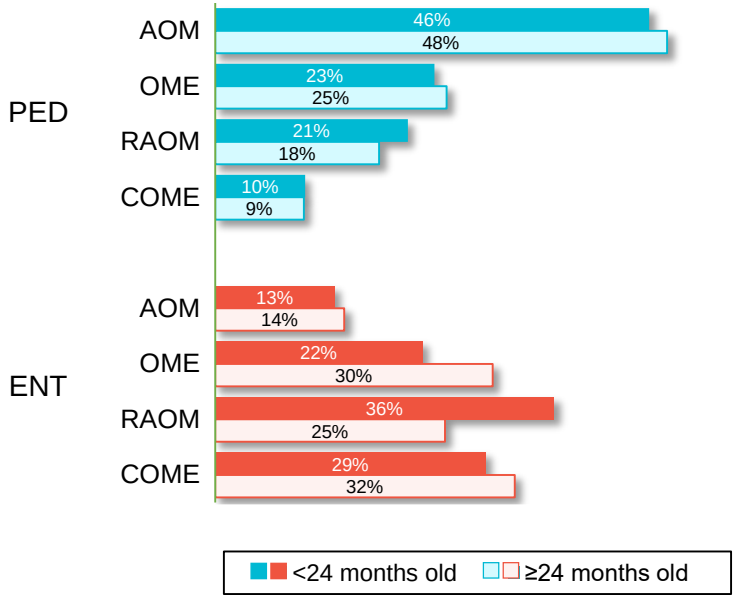
Novus conducted quantitative market research with 50 Pediatricians (“PED”) and 30 Otolaryngologists (“ENT”) to better understand the current management of otitis media and the potential utilization of OP0201 for otitis media

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

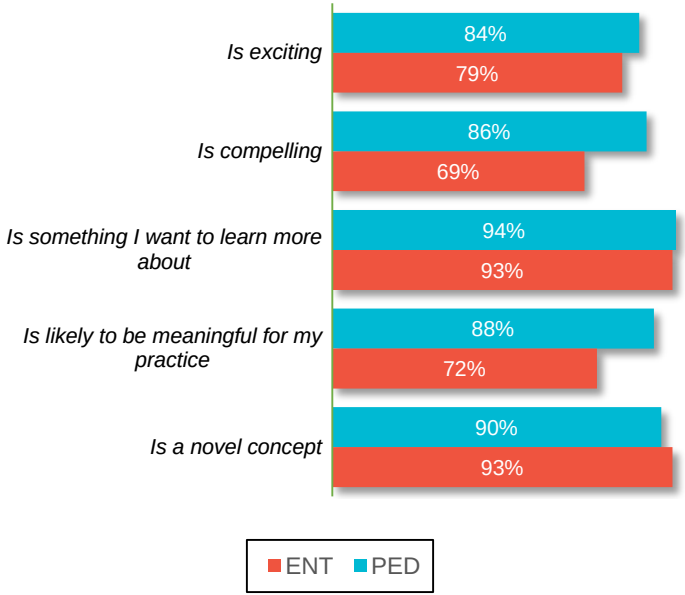
ENTs manage a greater amount of chronic/recurrent OM



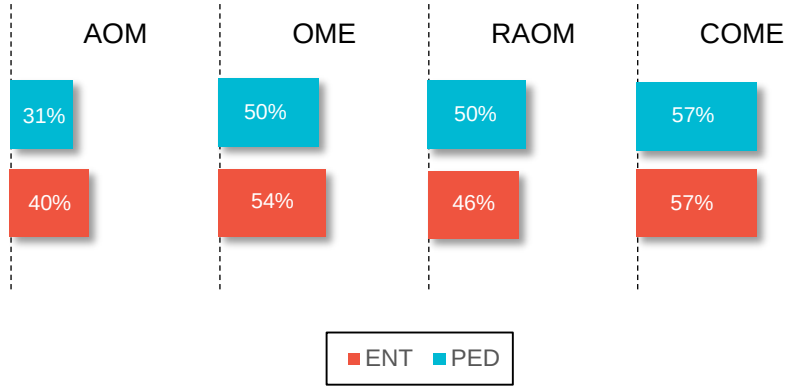
Novus Market Research May 2018 (data on file)

Physician Impression and Intended 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
(represents more than 6 million prescriptions annually)



Novus Market Research May 2018 (data on file)

Surfactant Program

Overview of Surfactant Program

- OP0201 is a novel nasal aerosol, 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 nasal spray designed to help restore and maintain Eustachian tube (ET) function
  - *Lowers ET surface tension and promotes "de-sticking"*
- Supportive data animal and human data
  - *Proof of concept successfully demonstrated in multiple animal species, plus supportive anecdotal evidence in humans*
  - *Single-dose safety established in phase 1 trial with healthy subjects (study C-001) and in patients with acute otitis media (study C-004)*
  - *Multi-dose safety and tolerability phase 1 trial in healthy subjects (C-002) and phase 2a trial in acute otitis media patients (C-006) ongoing*

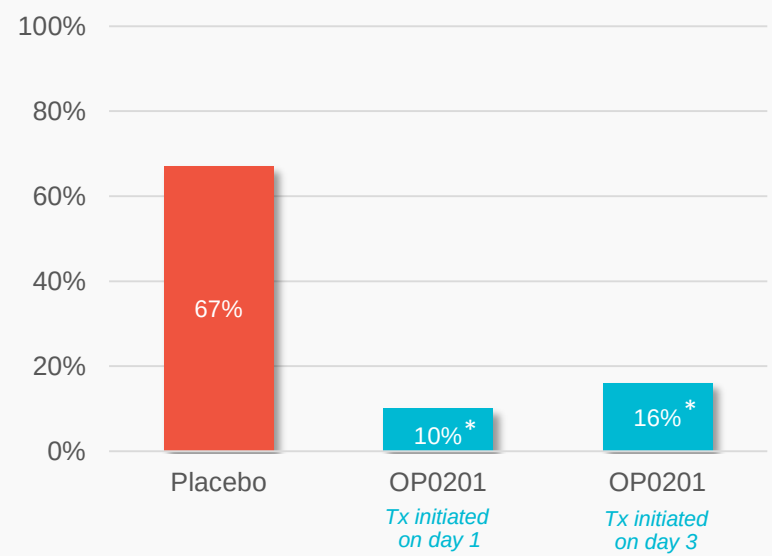
OP0201Preclinical Studies

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

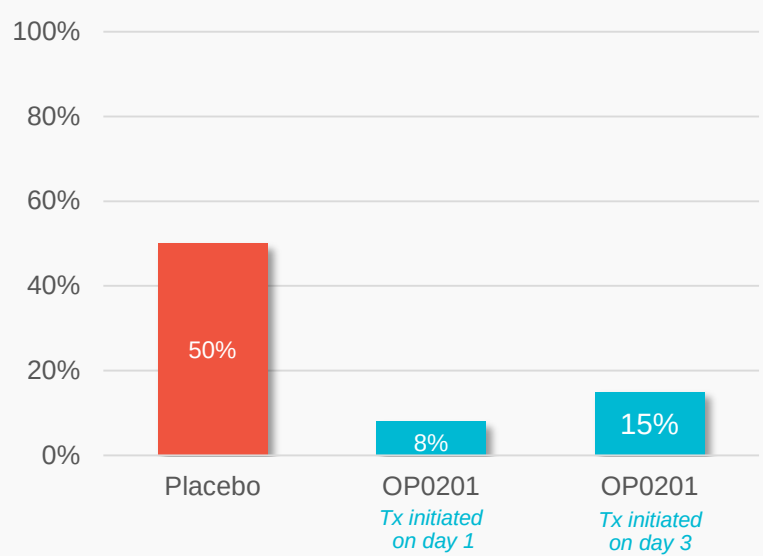
Chinchillas with AOM (Preclinical Study #3)

Middle Ears with Infection (Day 27)



* P = 0.002

Inner Ears with Inflammation (Day 8)



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

OP0201 Prior 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 years*
- *Captured as case studies and reported to FDA (also used in a patent application)*
- *Experience was consistent with animal data*

OM = otitis media; ETD = Eustachian tube dysfunction

OP0201 Phase 1 Studies (Single-Dose)

Study C-001

- Randomized, double-blind, cross-over, single-dose trial in healthy adults being subjected to changing atmospheric pressure in hyperbaric/hypobaric chamber (N=17)
- Designed to evaluate safety and tolerability, as well as explore Eustachian tube function within a 150-minute period following a single 20 mg intranasal dose
- Mean age of 25.8 years (52.9% female)
- 76.5% (13/17) who received OP0201 and 81.3% (13/16) 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

  The ENT physician investigator determined the adverse events were related to the chamber, not treatment
- No serious adverse events occurred during the study

Study C-004

- Randomized, double-blind, placebo-controlled, parallel-group single-dose trial in adults with acute otitis media and moderate or worse ear pain (N=24)
- Designed to evaluate safety and tolerability, as well as explore the relief of ear pain within a 60-minute period following a single 20 mg intranasal dose
- Mean age of 49.5 years (66.7% female)
- 16.7% (2/12) who received OP0201 and 50.0% (6/12) who received placebo experienced one or more adverse events
- The adverse events reported in the 2 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

OP0201 Phase 1 Study (14-Days of Treatment)

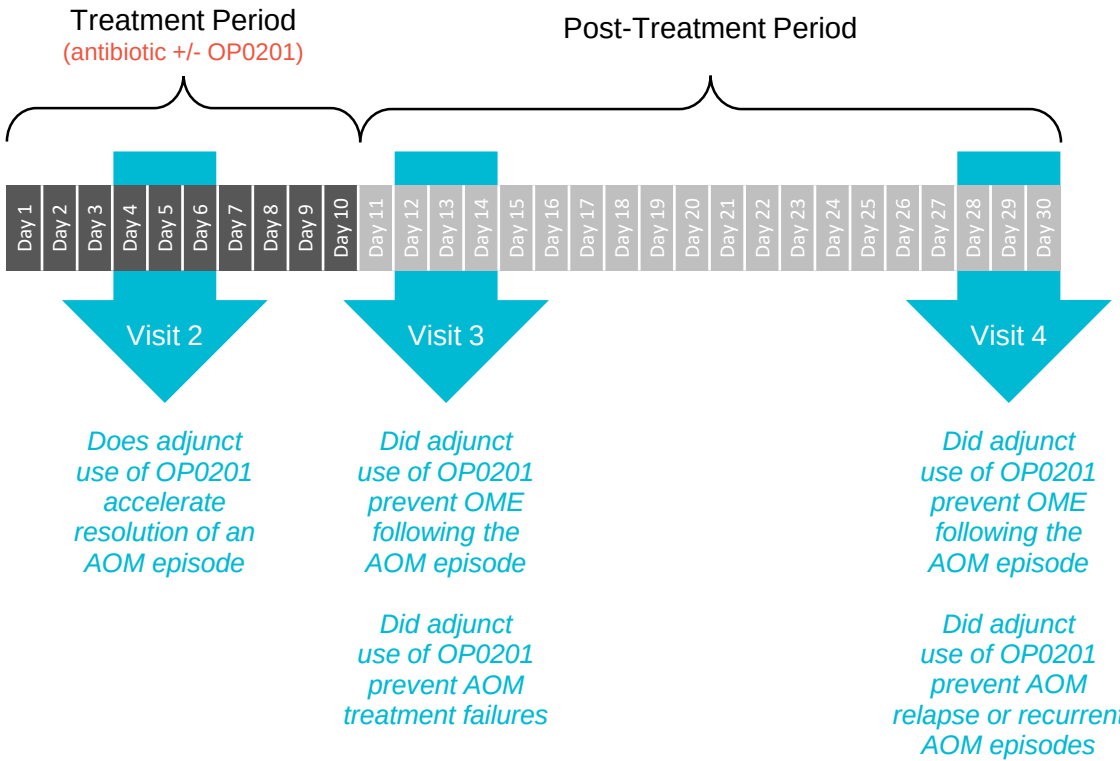
Study C-002

- Randomized, double-blind, placebo-controlled, parallel-group, dose-escalation trial in healthy adult subjects (N=30)
- Designed to evaluate safety and tolerability of daily intranasal administration of OP0201 over 14-days
  - *30 mg per day cohort (n=15)*
  - *60 mg per day cohort (n=15)*
- Enrollment completed with results expected June 2019

OP0201 Phase 2a Study (10 Days of Treatment)

Study C-006

- Randomized, double-blind, placebo-controlled, parallel-group trial in infants and children with acute otitis media (N~140)
- Designed to evaluate safety and tolerability, and explore efficacy of daily intranasal administration of OP0201 over 10-days
- Enrollment ongoing with results expected 1H 2020



OP0201 Future Phase 2 Clinical Trials

- Study C-007: Assessment of safety, tolerability and efficacy of OP0201 nasal aerosol as an adjunct treatment for ***acute otitis media*** in infants and children

- Study C-009: Assessment of safety, tolerability and efficacy of OP0201 nasal aerosol as a treatment for ***chronic otitis media with effusion*** in infants and children

Otitis Externa

Overview of Acute Otitis Externa

Inflammation and infection

Common condition of the external ear canal involving inflammation and infection

Symptoms

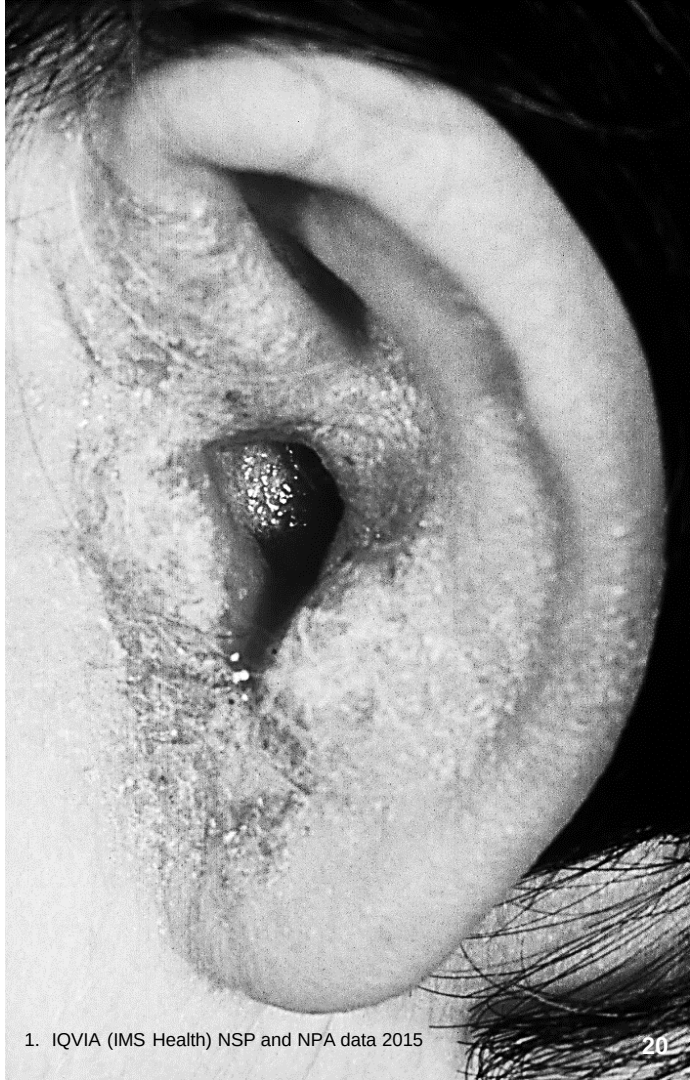
Symptoms include ear pain, itching, edema, reddening of the skin, and ear discharge

Chronic dermatologic conditions

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

Antibiotic prescriptions

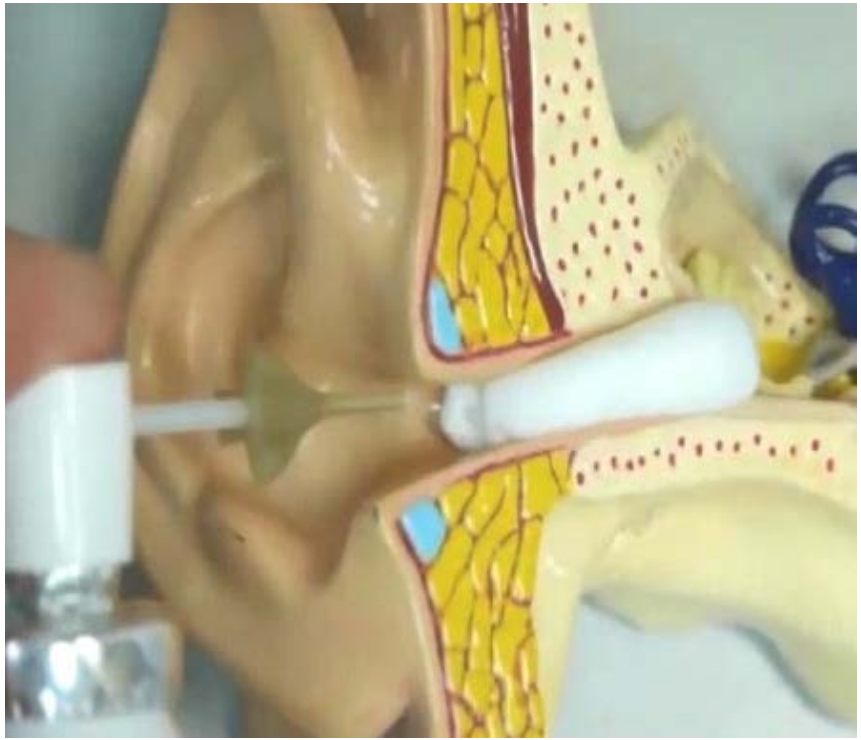
6.7 million antibiotic prescriptions written for the ear annually in the U.S.[1]



1. IQVIA (IMS Health) NSP and NPA data 2015

Foam Program

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 product (OP0101)

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

Completed initial formulation work on OP0201, a second-generation combination drug product 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)