



Novus | Corporate Presentation

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 annual report on Form 10-K for the year ended December 31, 2018 and 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 the treatment of otitis media or prevention of recurrent/chronic otitis media



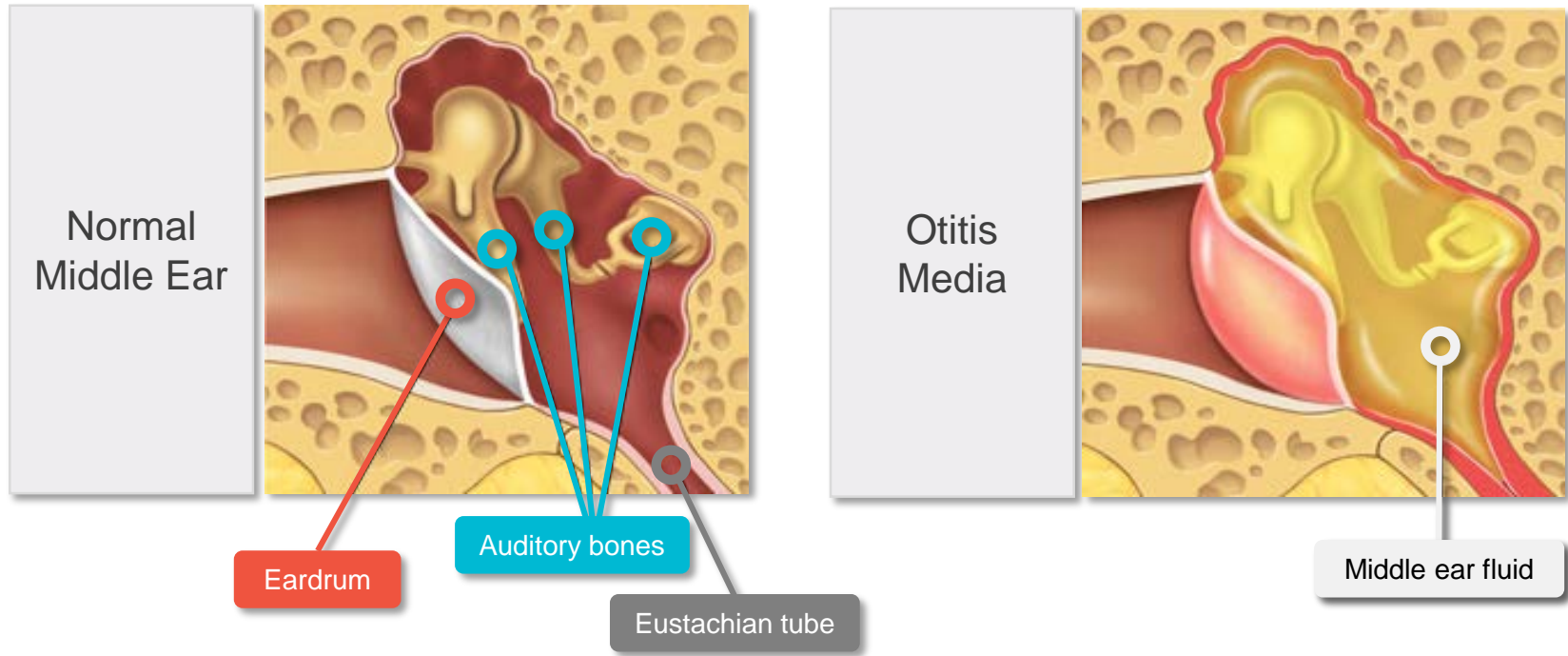
Near-term R&D milestone

Phase 2a clinical trial in phase 2a in infants and children with acute otitis media (AOM) in 1H 2020



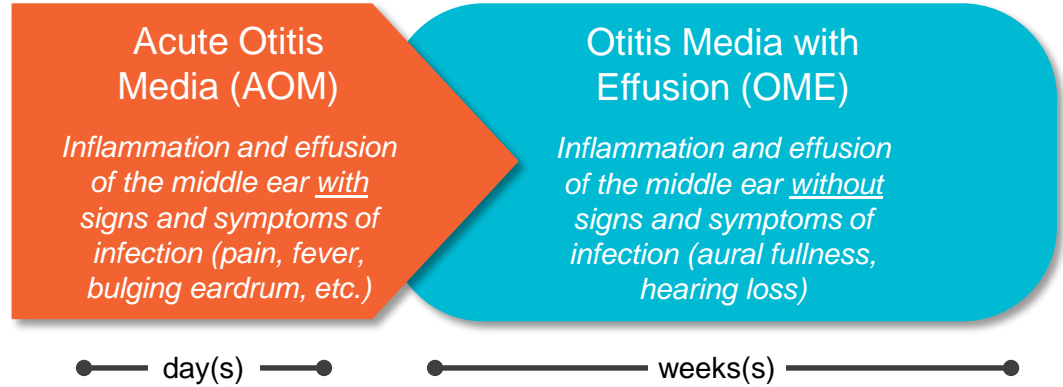
Otitis Media

Pathophysiology of Otitis Media





Definitions of Otitis Media



- ≥ 3 AOM episodes in the preceding 6-months or ≥ 4 AOM episodes in the preceding 12-months is recurrent acute otitis media (**RAOM**)
- OME that persists for ≥ 3 months from the date of onset/diagnosis is chronic otitis media with effusion (**COME**)

Current Management of Otitis Media

15+ Million

Annual visits to healthcare professions
in the U.S.¹

\$5+ Billion

Annual expenditure on the management
of otitis media in the U.S.²

Antibiotic frequently prescribed
(over-prescribed)

AAO-HNS, AAP, and AAFP guidelines
recommend against antibiotics in OME³

Insertion of ventilation tubes
into the eardrum has become
the standard of care

1 million surgeries performed annually
in the U.S.⁴



1. Tong et al. BMC Health Services Research (2018) 18:318

2. Casey et al, Clin Pediatr (Phila) 2014;53:865-873

3. Rosenfeld et al, Otolaryngol Head Neck Surg 2016;154(1S):S1-S41

4. Kesser et al, Surgery of Ventilation and Mucosal Disease 2010;(6):73-91



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*
 - *Supportive anecdotal evidence in humans*
 - *Safety and tolerability demonstrated in three phase 1 clinical studies*

OP0201 Preclinical Studies

Study	Design	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 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 the severity and duration of AOM

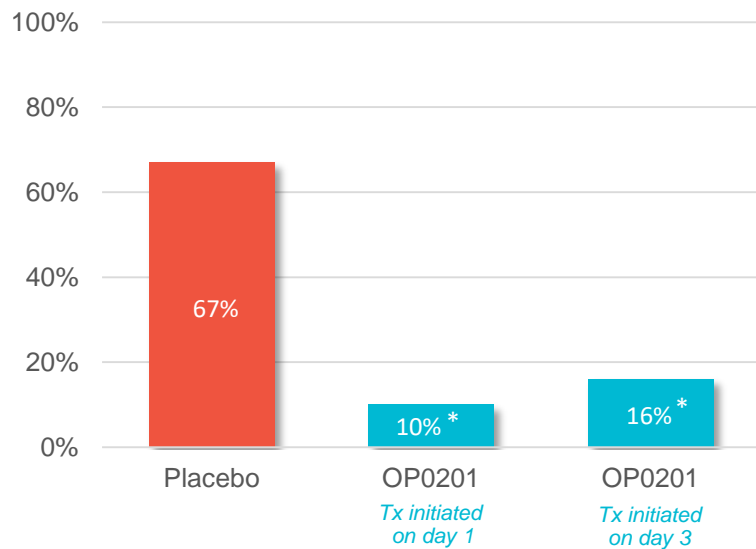
1. Chandrasekhar et al, Otology and Neurotology 2002;23:3-7

2. Venkatayan et al, Otolaryngology Head Neck Surgery 2001;124:388-93

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

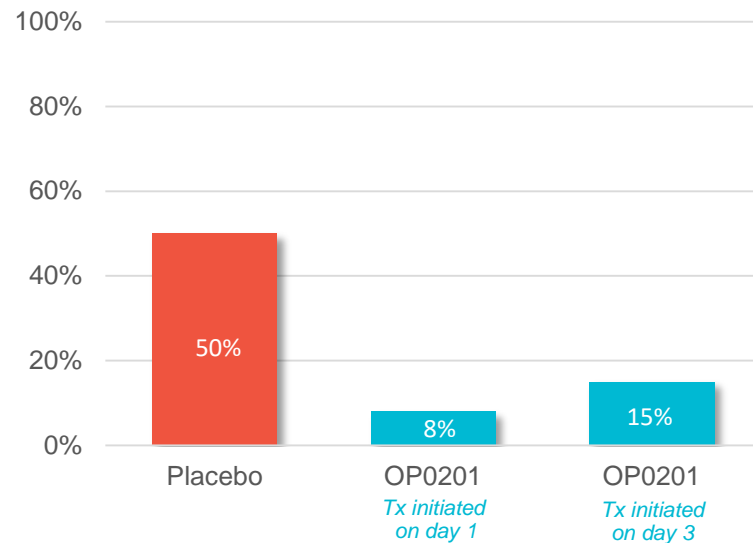
Chinchillas with AOM (Study #3)

Middle Ears with Infection (Day 27)



* P = 0.002

Inner Ears with Inflammation (Day 8)



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*

OP0201 Phase 1 Studies

Study	Design	Dosing	Result
C-001	Randomized, double-blind, cross-over trial in healthy adults under hyperbaric and hypobaric atmospheric conditions (N=17)	20 mg single-dose (150-min observation period)	Intranasal administration of a single 20 mg dose of OP0201 is safe and tolerable
C-002	Randomized, double-blind, placebo-controlled, parallel-group, dose-escalation study in healthy adults (N=30)	30 mg/day and 60 mg/day (14-days of treatment)	Intranasal administration of 30 mg/day and 60 mg/day of OP0201 is safe and tolerable
C-004	Randomized, double-blind, placebo-controlled, parallel-group trial in adults with AOM and ear pain (N=24)	20 mg single-dose (60-min observation period)	Intranasal administration of a single 20 mg dose of OP0201 is safe and tolerable

OP0201 Study C-002 Safety and Tolerability

Overview of Incidence of Treatment-Emergent Adverse Events (Safety Analysis Set)

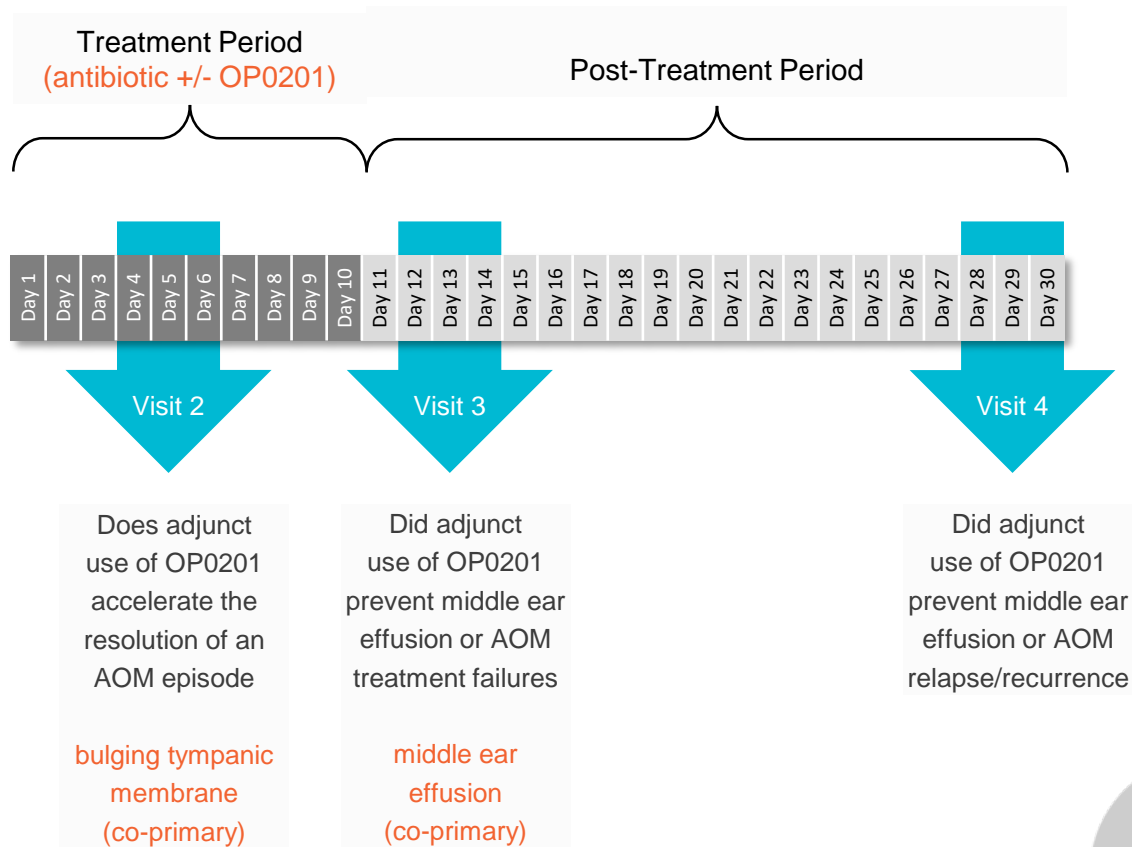
	30 mg/day OP0201 (N=12)	60 mg/day OP0201 (N=12)	All OP0201 (N=24)	All Placebo (N=6)	All Treated (N=30)
Any TEAE	5 (41.7%)	9 (75.0%)	14 (58.3%)	4 (66.7%)	18 (60.0%)
Related TEAEs	4 (33.3%)	8 (66.7%)	12 (50.0%)	4 (66.7%)	16 (53.3%)
Serious TEAEs	0	0	0	0	0
Related Serious TEAEs	0	0	0	0	0
Severe TEAEs	0	0	0	0	0
TEAEs resulting in study drug discontinuation	0	0	0	0	0
TEAEs resulting in death	0	0	0	0	0

TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event

OP0201 Phase 2a Study (AOM Patients)

Study C-006

- ✓ Randomized, double-blind, placebo-controlled, parallel-group trial in infants and children with acute otitis media (AOM)
- ✓ Designed to evaluate safety and tolerability, and explore efficacy of OP0201 when administered as an adjunct to oral antibiotics
- ✓ Enrollment ongoing with results expected 1H 2020



OP0201 Future Phase 2 Clinical Studies

- Study C-008: Assessment of safety, tolerability and efficacy of OP0201 nasal aerosol as an adjunct treatment for acute otitis media in infants and children
 - *Final study design pending result from ongoing study C-006*
- 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
 - *September 2019 meeting with FDA to discuss study protocol*

Physician Management of Otitis Media

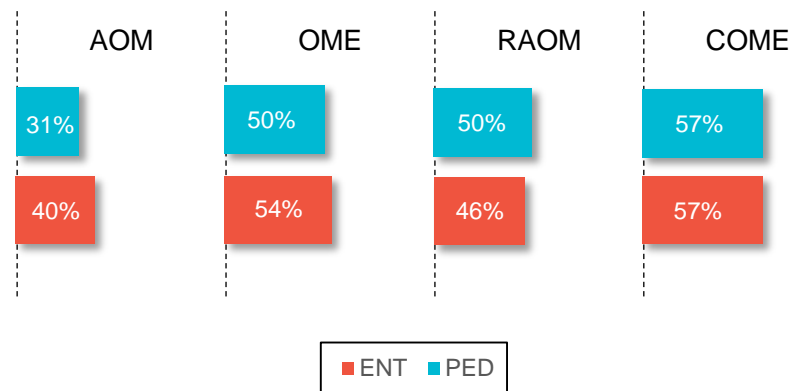
Novus conducted quantitative market research with 50 Pediatricians (“PED”) and 30 Otolaryngologists (“ENT”) to better understand the current management of otitis media and the potential utilization of OP0201 for otitis media

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

PED/ENTs intend to utilize OP0201 across all OM types
(represents more than 6 million prescriptions annually)





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