



**AM-301**

**Mitigating risk from  
exposure to airborne  
viruses and allergens**



# Forward-looking Statements

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*This presentation may contain statements that constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical facts and may include statements that address future operating, financial or business performance or Auris Medical’s strategies or expectations. In some cases, you can identify these statements by forward-looking words such as “may”, “might”, “will”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “projects”, “potential”, “outlook” or “continue”, or the negative of these terms or other comparable terminology. Forward-looking statements are based on management’s current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include, but are not limited to,*

*the approval and timing of commercialization of AM-301, Auris Medical’s need for and ability to raise substantial additional funding to continue the development of its product candidates, the timing and conduct of clinical trials of Auris Medical’s product candidates, the clinical utility of Auris Medical’s product candidates, the timing or likelihood of regulatory filings and approvals, Auris Medical’s intellectual property position and Auris Medical’s financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions or changes to Auris Medical’s capital structure, including future securities offerings. These risks and uncertainties also include, but are not limited to, those described under the caption “Risk Factors” in Auris Medical’s Annual Report on Form 20-F for the year ended December 31, 2020, and in Auris Medical’s other filings with the SEC, which are available free of charge on the Securities Exchange Commission’s website at: [www.sec.gov](http://www.sec.gov). Should one or more of these risks or*

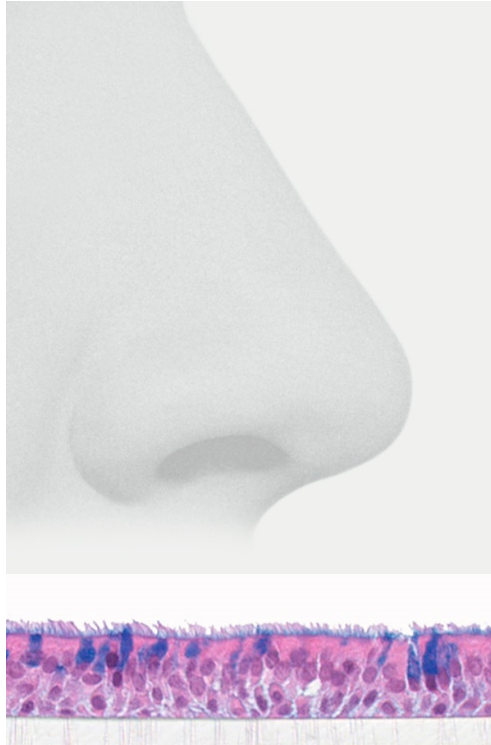
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- **Product profile**
  - **Allergy data**
  - **Viral infection data**
  - **Commercialization**
  - **Market potential**

# Agenda

# Danger in the Air

Every day you breathe in just over 2000 gallons of air...



Nasal mucosa

- Up to 90% of air inhaled via the nose
- Exposure to airborne virus, bacteria, allergen or dirt particles
- Nasal mucosa acts as a protective barrier against these particles
  - Secretes mucus which traps particles
  - Clearance via the throat
- Occasionally overwhelmed or breaks down
  - Nasal dryness or irritation
  - Mucosal damage
- Allergic reactions (hay fever, dust mite allergies...)
- Viral infections (influenza, common cold, SARS, MERS...)

# How AM-301 Acts

Complements the natural defense of the nasal mucosa

Triple protective effect aids in the defense against airborne particles



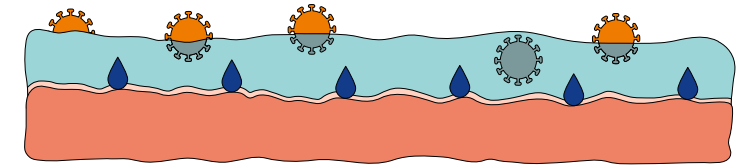
**Protects**  
as a physical barrier  
the nasal mucosa



**Traps**  
airborne particles through  
electrostatic effects



**Humidifies**  
the nasal mucosa and  
thus aids its functionality



- Protective barrier
- Nasal mucosa
- Binding of virus & allergen particles
- Humidification of nasal mucosa

# Key Features of AM-301

A nasal spray for convenient self-protection



## Trap to remove

Capturing particles  
for discharge with mucus

### → It's more than a barrier

- Trapping various airborne virus, allergen or dirt particles
- Electrostatic effects work a priori with any charged particle



## Drug free

Contains no active  
pharmaceutical ingredient

### → It's a medical device

- No pharmacological, metabolic or immunologic activity
- Only physical effects



## Preservative free

Safety by design including  
special spray pump

### → It's well tolerated

- Commonly used preservatives tend to harm mucus membranes
- Commonly used preservatives may give unpleasant sensation



## Protects for $\geq 3$ hours

Gel designed for extended  
nasal residence time

### → It's convenient

- Gel becomes liquid upon shaking, allowing to spray it
- Liquid turns into gel again when applied into nose

# AM-301 Effectively Alleviates Allergy Symptoms

Primary efficacy endpoint met in clinical pollen challenge

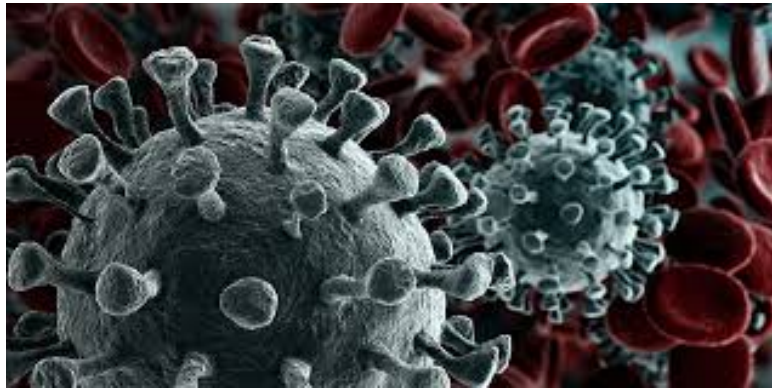


Allergen challenge chamber

- Open-label randomized cross-over study
- 36 patients with allergic rhinitis to grass pollen
- Single dose of AM-301 spray or comparator prior to 4 hours of controlled pollen exposure
- Total Nasal Symptom Score (TNSS)
  - Nasal congestion, itching, sneezing, rhinorrhea
  - Preliminary analyses show non-inferiority of AM-301 to marketed comparator
- Rapid onset of protective effect
- Protection for at least 3 hours
- Well tolerated

# AM-301 Decelerates SARS-CoV-2 Titer Growth

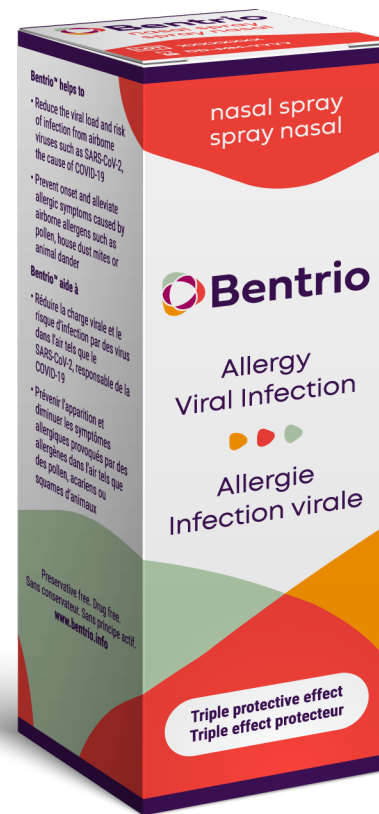
First *in vitro* data from application post infection



- Reconstituted human nasal epithelium model
  - Functional nasal mucosa
  - Without help from immune system or mucociliary clearance
  - Read-out through median Tissue Culture Infectious Dose, TCID<sub>50</sub>, in Vero cells
- Daily treatment with AM-301 starting 24 or 30 hours post inoculation with SARS-CoV-2
  - Saline- and vehicle-treated and untreated controls
- Statistically significant deceleration of the viral titer growth compared to controls
  - p-value <0.01, linear mixed-effects model
- At Day 4 viral titers were 73.7-94.5% lower than controls

# Introducing Bentrio™

Our brand name for marketing AM-301



# Moving Towards Bentrio™ Commercialization

Launch planned in selected European countries in late Q2 2021



## Europe

- On track to meet essential requirements for marketing
- Roll-out in selected countries starting in June 2021
  - On- and offline distribution channels
- Expand market coverage rapidly during second half of 2021
- Collaborations with future licensing partners
- Significant, scalable contract manufacturing capacity

## USA

- Intended use in allergy: 510(k) submission to FDA expected at around the time of CE mark conformity
- Intended use in viral infections: ongoing dialogue with Agency on applicable regulatory pathway

# Market Potential for Bentrío™

## Addressing frequent conditions

### Allergies

- About 7.8% of people 18 and over in the US have hay fever [Schiller et al., 2010](#)
- 11.1 million visits to physician offices with primary diagnosis of allergic rhinitis [National Ambulatory Medical Care Survey](#)
- \$4 billion market size for OTC allergy medicines in US in 2020 [www.ibisworld.com](http://www.ibisworld.com)

### Viral infections

- Human rhinovirus (HRV) is most common cause of upper respiratory tract infection
- US revenues for cold and cough remedies are expected > \$12 billion in 2021 [www.statista.com](http://www.statista.com)
- Influenza has resulted in 9-45 million illnesses, 140,000-810,000 hospitalizations and 12,000-61,000 deaths annually since 2010 [Centers for Disease Control and Prevention](#)
- Covid-19: 136.4 million cases and 2.94 million deaths to date

