# lonear Technologies

Innovative medical devices for ear & hearing disorders

Ida Pavlichenko, PhD

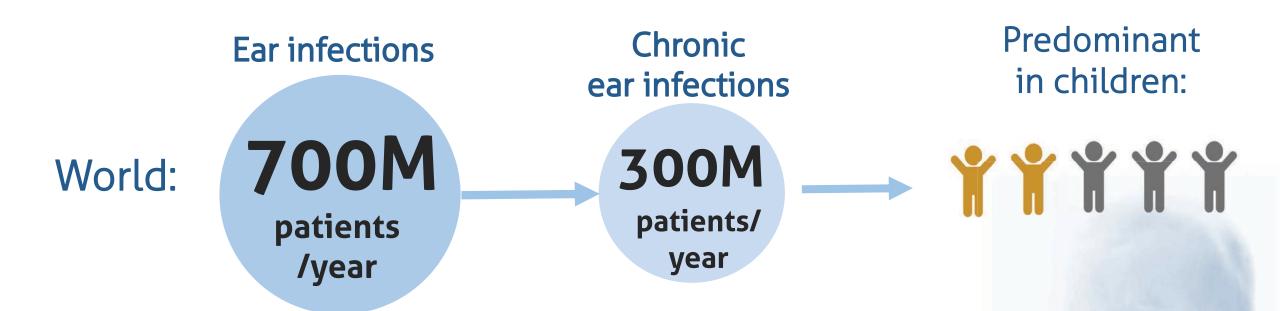
ida@pionear-tech.com



Bianca was in constant pain because of chronic ear infections and persistent fluid in her ears...



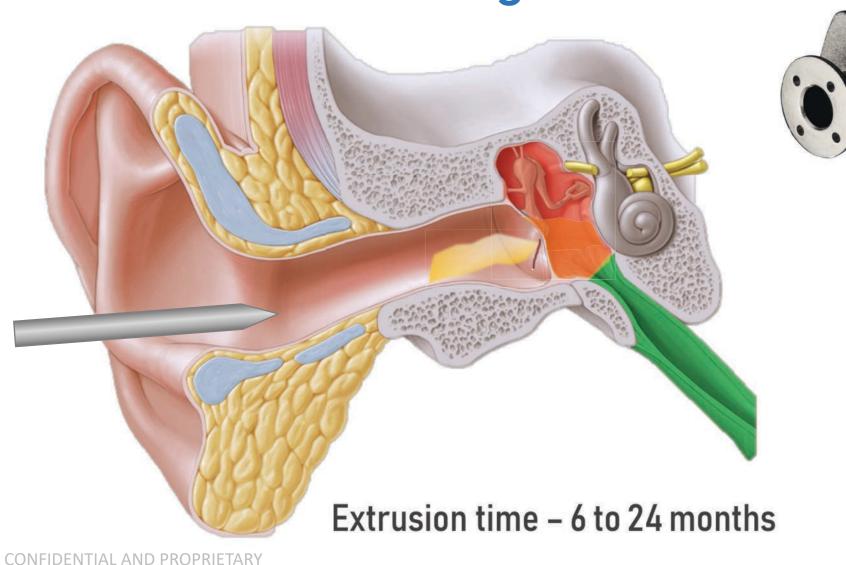
# Ear infections are a major global problem with high socioeconomic impact



#1 cause of

- healthcare visits (>\$10B global cost)
- irreversible hearing loss (in ~60% of patients)

### In US, 40% of kids develop Chronic Condition 7-10% undergo tube insertion surgery



**1M** 

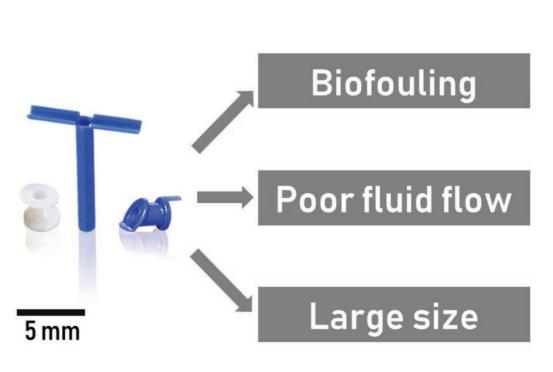
patients/year in US receive

tympanostomy tubes

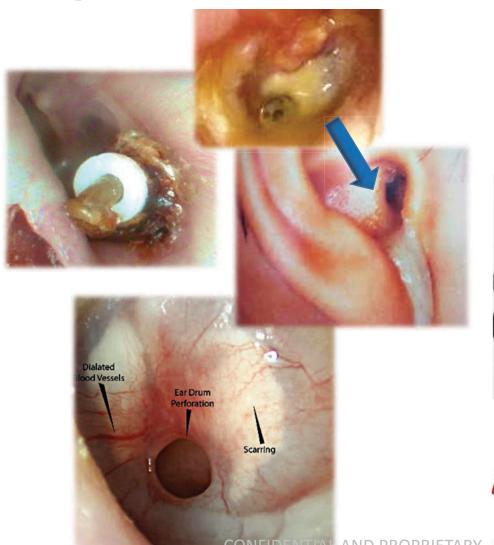




## Current tubes have post-surgical complications in up to 75% of cases



- Unnecessary revision surgeries under general anesthesia
- Added healthcare cost





Silicone tube



#### PionEar device solves all current problems

✓ PionEar's solution:

✓ Proprietary material & design:

1. No biofouling

2. Enhanced fluid flow

3. Small size



Provisional application filed in March 2018

• PCT application filed in March 2019

Winners 2018:





- Class II device
- CPT code available
- Based on all-FDA approved materials



#### Strong value for all stakeholders











prevents
thousands of
unnecessary
surgeries

saves
millions of hours
in the
operating room

saves

\$ billions

in direct &

indirect costs

Ear infections market

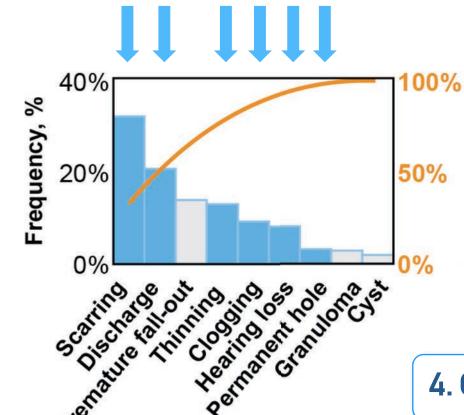


Hearing & balance disorders market



#### Verified High Safety and Efficacy of PionEar Tubes

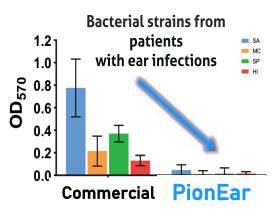
PionEar targets all major failure mechanisms

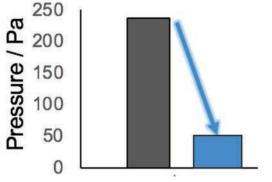


1. Suppressed blood, bacterial, and cellular adhesion

2. Effective therapeutic delivery

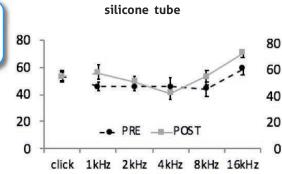
3.50% smaller size





4. Confirmed safety



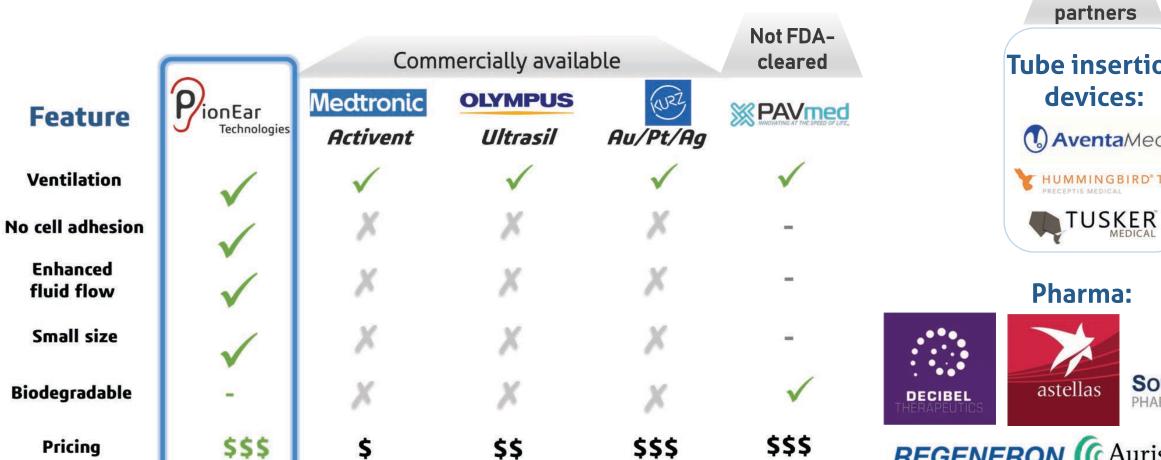


**ABR: Commercial** 



click 1kHz 2kHz 4kHz 8kHz 16kHz

### PionEar's product is superior to its alternatives







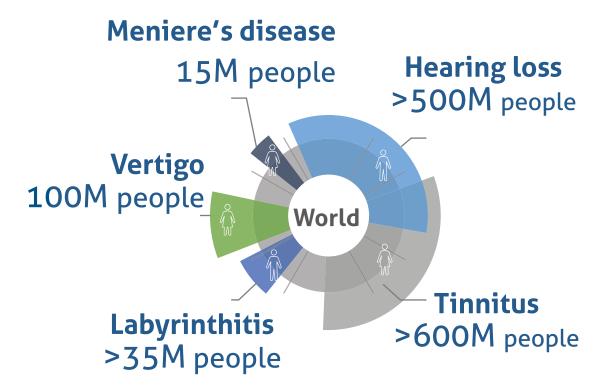




#### Platform technology that enables future expansion

PionEar will address the large unmet need in drug delivery for:





Other medical applications:









### Short timeline to market & strong value

2018

2019

2020

2021

2022-23



#### Secured \$435K

- R&D
- In-vivo/vitro validation



#### Seeking for the Seed Funding: \$3M

- GMP manufacturing/GLP studies
- First FDA 510k clearance
- In-man studies for additional claims in second 510K
- Marketing/Distribution





#### Committed and diverse team to solve the problem

#### **Founders:**



Ida Pavlichenko, PhD
President & Co-founder



Prof. Joanna Aizenberg,
PhD
Co-Founder



Medical device advisor:



Business advisor:



Robert Cunningham, BS BD Advisor















October 2018

**March 2019** 

MC



May 2018



**July 2018** 

#### **GRAND PRIZE**

Gold Winner 2018

**MASSCHALLENGE** 

Mass Innovation **Nights** 



#### **GRAND PRIZE**









Thank you!

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