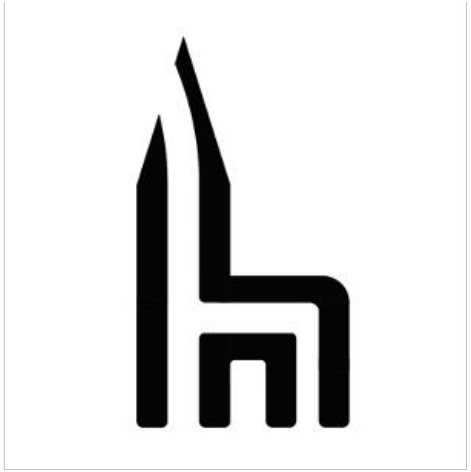


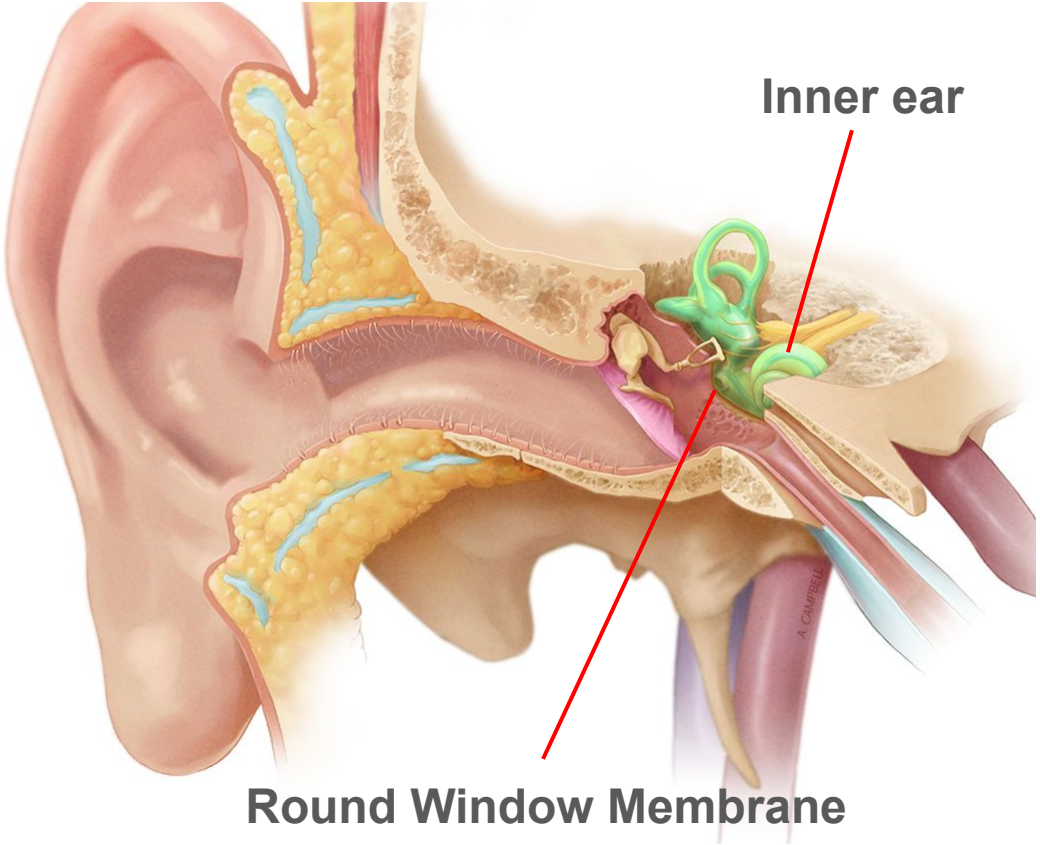
# Haystack Medical

Ultra-sharp needles to diagnose and cure hearing and balance disorders

# Inner ear maladies lack proper treatment and diagnosis

- 90% of all hearing loss has **underlying causes in the inner ear**. (>30 million in the US)
- **Diagnosis is limited** to excluding causes outside the inner ear.
- Treatments are symptomatic and **do not address underlying causes**.

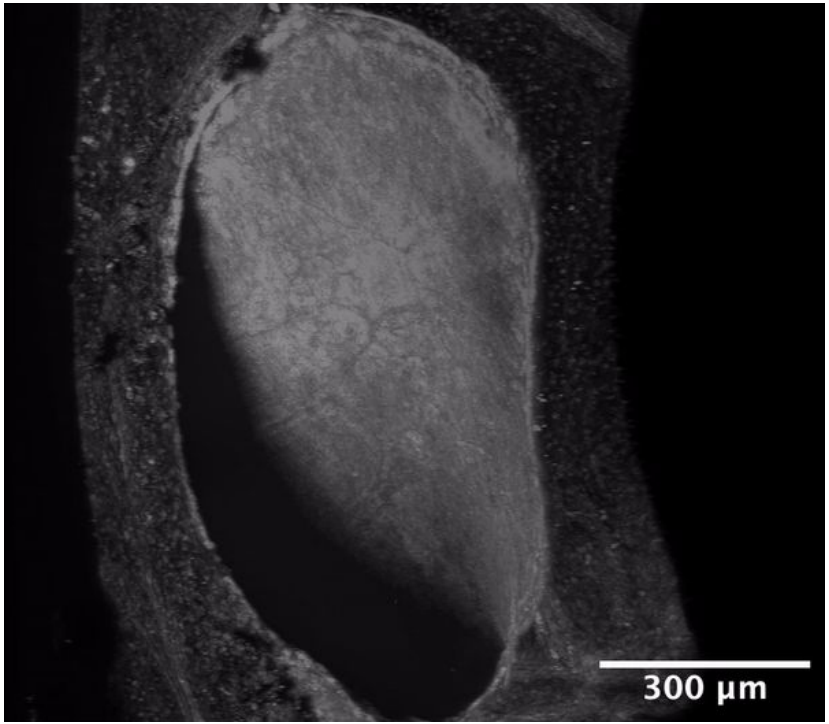
# Access to inner ear is essential for diagnostics & treatment




- Systemic access is not possible because inner ear is on the other side of blood brain barrier.
- Inner ear is fully closed with hard bone, except for one membranous barrier: **the round window membrane**.

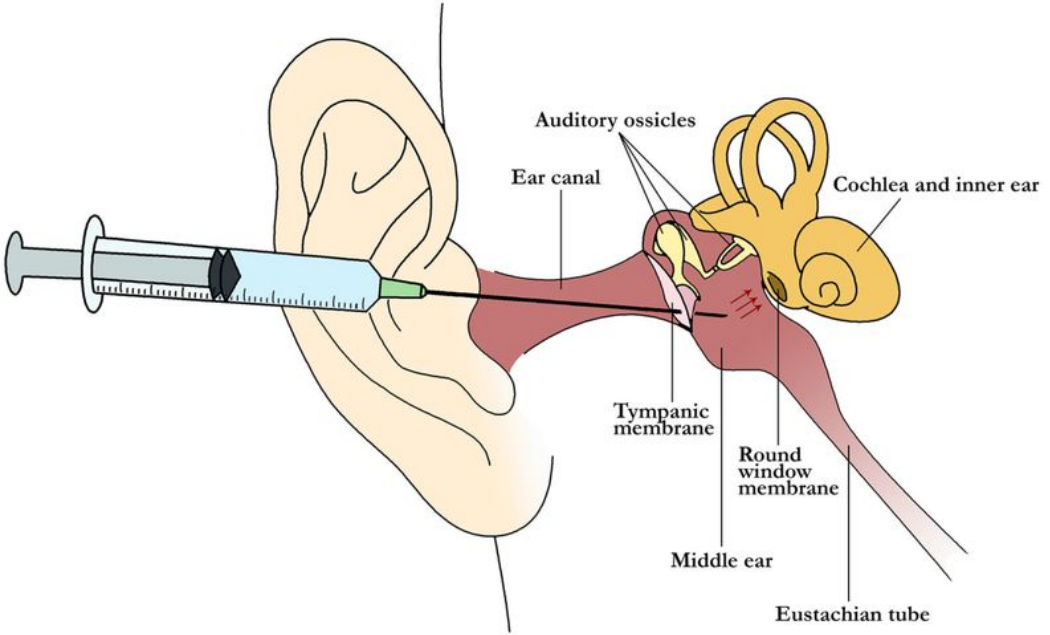
# Round window membrane is a challenging barrier

- Round window membrane is small, about 1 mm across.
- It is very delicate, regular tools cannot be used to perforate it safely.
- There is a **low and variable rate of diffusion** across it.
  - Anatomic variability causes imprecise dosing.
  - Membrane is selectively permeable, only lets certain kinds of molecules in, at a limited pace.

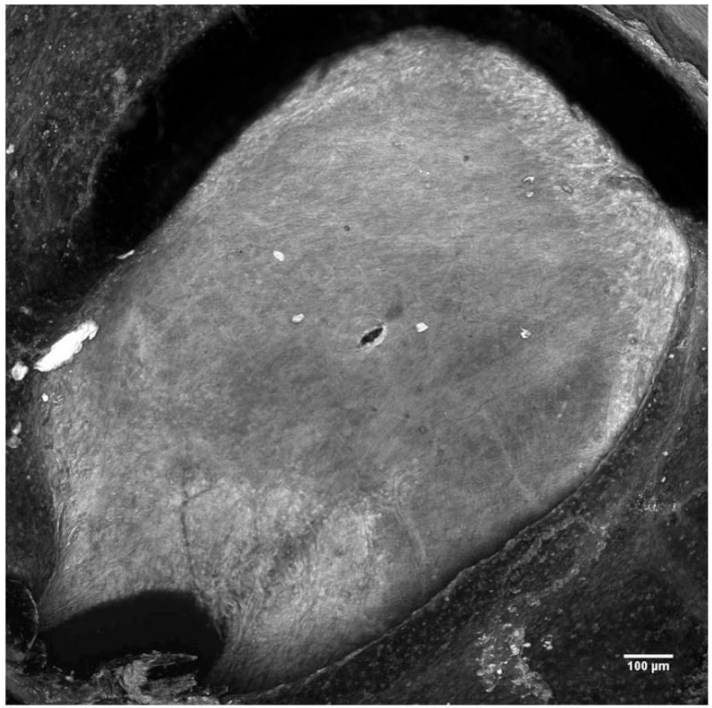


# State of the art - current methods are not effective

- Diagnosis is made through exclusion.
- Treatments are delivered by intratympanic injection into the middle ear space.
- Drugs are expected to diffuse across the round window membrane.



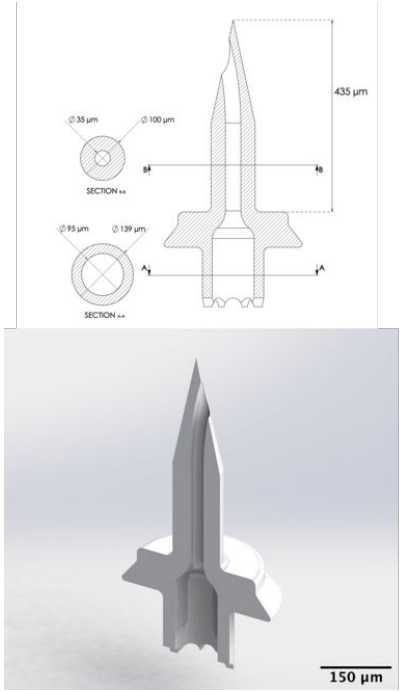
# Our needles open a window into the inner ear, safely

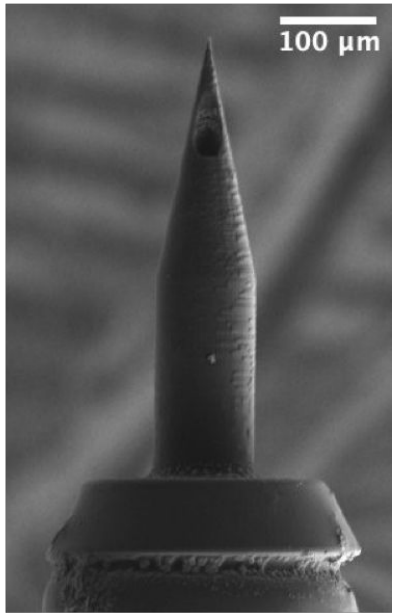



- Our ultra-sharp, purpose specific needles:
  - minimize damage to the round window membrane.
  - separate rather than cut connective fibers of the membrane.
  - enable fast healing. (48 hours)
  - cause no audiologic or anatomical consequences.

Aksit et al. (2018) Novel 3D-printed hollow microneedles facilitate safe, reliable, and informative sampling of perilymph from guinea pigs. Biomed Microdevices.

# Haystack needles: first ever safe sampling of inner ear fluids



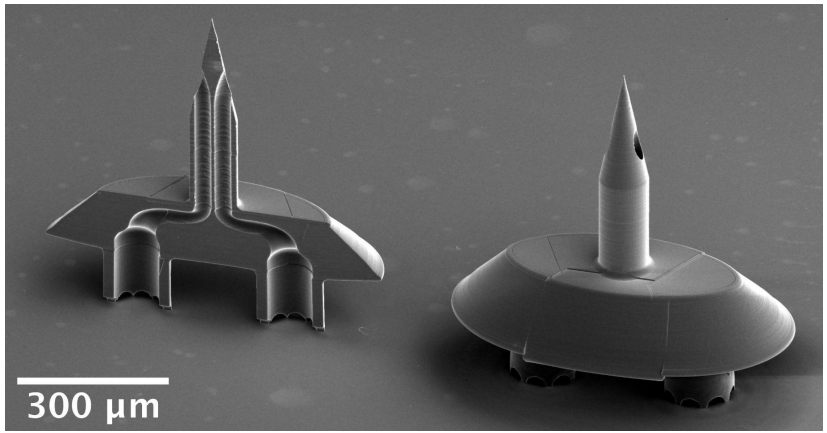




- Our hollow needles are:
  - about the same thickness as human hair.
  - capable of aspirating 1µL of perilymph for diagnostic testing: sufficient for analysis, and shown to be safe in guinea pigs animal model.

Szeto et al. (2021) In-vitro perforation of the round window membrane via direct 3-D printed microneedles. Hear Res.

# Haystack needles: first ever minimally invasive direct injection of therapeutics into the inner ear

- Precise dosing of therapeutics via direct injection, regardless of molecular properties.
- Can simultaneously inject and aspirate fluid, enabling injections of large volumes.
- Maintains constant fluid volume and pressure in the cochlea.



# Our technology opens up possibilities for new therapeutics

- Currently potential therapies are limited to molecules that can readily diffuse through the RWM.
- Our needles can deliver larger and polar molecules.
- Possible by removing pharmacokinetic barriers, leading to drug discovery for the inner ear.

# Market opportunity is massive

**Beachhead market:**

Meniere's disease & sudden sensorineural hearing loss

~300k patients see physicians each year

Insurance and billing code compatible

**Current size (attainable, short term): >$500M in the U.S.**

**Looking forward: visionary market potential is >$30B**

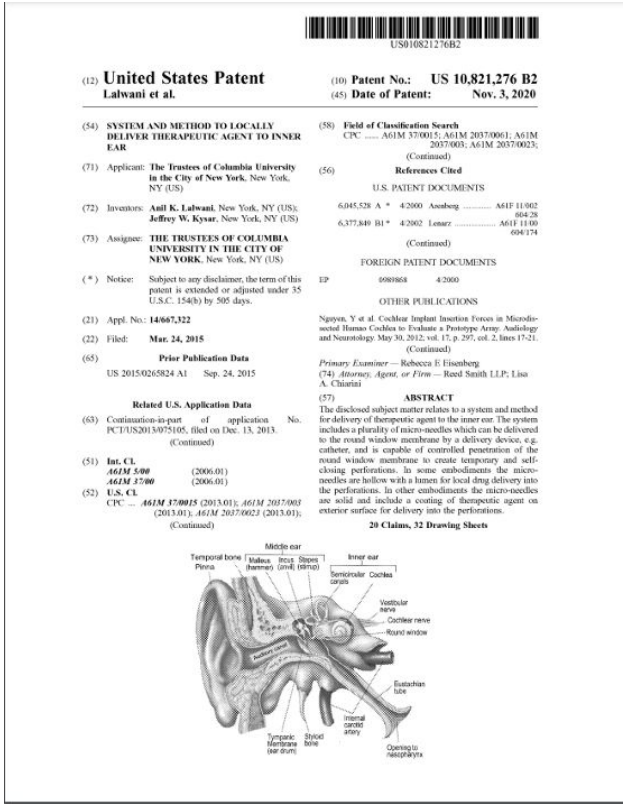
| | |
|---|---|
| Age related hearing loss: | ~30 million people in the U.S. |
| Severe tinnitus: | ~6 million people in the U.S. |

# Haystack Medical value proposition

- **World renowned team:** Building upon a decade of work and expertise.
  - Funded by foundation, NIH and DoD grants.
  - **20+ peer reviewed journal publications** by the team on this project alone.
- **Exquisite IP portfolio**: numerous patents and patent applications.
- **Novel hardware:** Inventions and technologies produced specifically for the inner ear.
- **Unique diagnostic capabilities:** Whole new source of data available.
- **Potential for fully aligned novel therapeutics.**

# Strong IP portfolio

- 2 granted patents, covering:
  - Plurality of microneedles for round window membrane access.
  - Serrated needle design for opening large perforations into the round window membrane.
- 9 pending applications, covering newer developments and improvements to needle design and application systems.
- Many more waiting to be filed.



US010821276B2

(12) **United States Patent**
**Lalwani et al.**

(10) **Patent No.: US 10,821,276 B2**
(45) **Date of Patent: Nov. 3, 2020**

(54) **SYSTEM AND METHOD TO LOCALLY DELIVER THERAPEUTIC AGENT TO INNER EAR**

(71) Applicant: **The Trustees of Columbia University in the City of New York**, New York, NY (US)

(72) Inventors: **Anil K. Lalwani**, New York, NY (US); **Jeffrey W. Kysar**, New York, NY (US)

(73) Assignee: **THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK**, New York, NY (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 505 days.

(21) Appl. No.: **14/667,322**

(22) Filed: **Mar. 24, 2015**

(65) **Prior Publication Data**

US 2015/0265824 A1 Sep. 24, 2015

**Related U.S. Application Data**

(63) Continuation-in-part of application No. PCT/US2013/075105, filed on Dec. 13, 2013.
(Continued)

(51) **Int. Cl.**
***A61M 5/00*** (2006.01)
***A61M 37/00*** (2006.01)

(52) **U.S. Cl.**
CPC ... ***A61M 37/0015*** (2013.01); *A61M 2037/003* (2013.01); *A61M 2037/0023* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ..... A61M 37/0015; A61M 2037/0061; A61M 2037/003; A61M 2037/0023;
(Continued)

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(Continued)

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(Continued)

*Primary Examiner* — Rebecca E Eisenberg
(74) *Attorney, Agent, or Firm* — Reed Smith LLP; Lisa A. Chiarini

(57) **ABSTRACT**

The disclosed subject matter relates to a system and method for delivery of therapeutic agent to the inner ear. The system includes a plurality of micro-needles which can be delivered to the round window membrane by a delivery device, e.g. catheter, and is capable of controlled penetration of the round window membrane to create temporary and self-closing perforations. In some embodiments the micro-needles are hollow with a lumen for local drug delivery into the perforations. In other embodiments the micro-needles are solid and include a coating of therapeutic agent on exterior surface for delivery into the perforations.

**20 Claims, 32 Drawing Sheets**

# Strong team — BoD and SAB under development

## Aykut Aksit, PhD

• Postdoctoral Scientist in Mechanical Engineering, Columbia University
• Expertise in microfabrication and specifically, ultra-sharp needles for inner ear access.

## Jeffrey Kysar, PhD

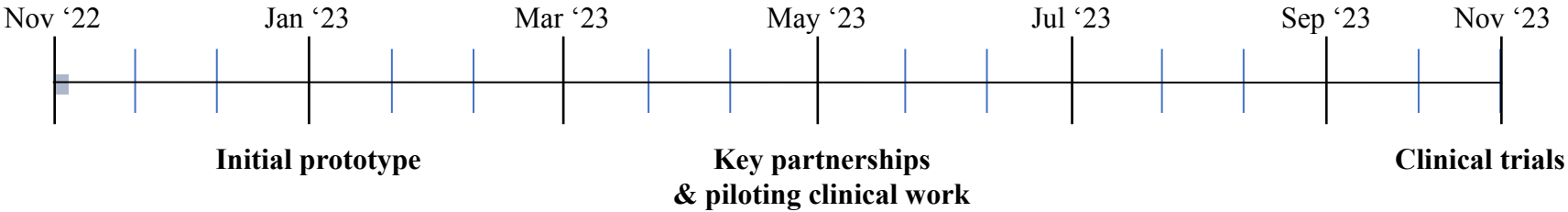
• Professor of Mechanical Engineering, Columbia University
• Expertise in micro/nanoscale behavior and mechanical properties of materials
• >15 patents & patent applications

## Anil Lalwani, MD

• Professor of Otolaryngology, Columbia University
• Clinical expertise in intracochlear access, auditory physiology, and genetic therapies
• >180 peer-reviewed articles

# What we need

- **We're raising $4M** for Haystack Medical's seed round. Burn = $200k/month.
- Within **12 months** we will:
  - Show feasibility of the device to be used in an office setting, with minimal training.
  - Begin **clinical trials**.
  - Establish key partnerships to streamline our go to market strategy.

# Thank you!

Contact: aykut@haystackmedical.com