

1. Company name and website
2. Team member names, titles and contact information, expertise
3. Executive Summary (includes a unique value proposition, IP status, target audience, traction, business strategy, team)
4. Deck
5. Video links
6. Summary - 3-5 sentence description
7. Summary of your ideal MassVX CEO (e.g. list your immediate needs and timing, ideal skills, compensation, industry sectors, interests)

1. PionEar Technologies, Inc.

www.pionear-tech.com (not active yet)

<https://wyss.harvard.edu/technology/liquid-infused-tympanostomy-tubes/>

2. Team

Dr. Ida Pavlichenko, President, Director and Co-Founder,
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McKay 426, 9 Oxford St, Cambridge, MA, 02138
Phone: 7035059901

Dr. Ida Pavlichenko is a technology development fellow at the Harvard Wyss Institute for Biologically Inspired Engineering, and a CEO and Co-Founder of PionEar Technologies, Inc., a spin-out of the Wyss Institute. Led by Dr. Pavlichenko, in 2018, PionEar Technologies has received the Grand Prize in the Health and Life Sciences Track at the Harvard President's Innovation Challenge; two Validation Grants for Technology Commercialization in 2018 and 2019; the Audience Choice Grand Prize at the 115th Mass Innovation Nights; and the Gold Prize at the MassChallenge, and was selected by the Massachusetts Biotechnology Council's MassCONNECT program and MassMEDIC Ignite 2019. PionEar's novel tympanostomy tube technology co-invented by Dr. Pavlichenko, has won the Collegiate Innovators Competition by National Hall of Fame and the United States Patent and Trademark Office in November 2018.

Previously, Dr. Pavlichenko was a postdoctoral fellow in the group of Prof. Joanna Aizenberg at the Harvard John A. Paulson School of Engineering and Applied Sciences, where she was applying the principles of bio-inspired engineering for the design and development of novel medical devices and AI-based photonic sensors, and spearheading numerous complex collaborative efforts with academia, industry, government, and start-ups, and was a co-inventor on several patents. Dr. Pavlichenko earned her PhD (*summa cum laude*) from the Ludwig Maximilian University of Munich, Germany in 2014 and an MSc (*summa cum laude*) from the Lomonosov Moscow State University, Russia in 2010.

Prof. Joanna Aizenberg, Director and Co-Founder
joanna@pioneer-tech.com,
Room 229, 29 Oxford St, Cambridge, MA, 02138

Joanna Aizenberg is a pioneer in the rapidly developing field of bio-inspired materials science and engineering - a branch of science that uses biological principles to solve complex materials and design challenges - and has led the development of numerous advanced, innovative surfaces and devices with transformative impact across disciplines and settings. She has nearly two decades of experience developing novel strategies for inorganic deposition processes and fabricating structured surfaces, with a level of multiscale control not previously achievable. She also has multipronged expertise at the bio-nano interface, with a substantial track record in designing materials approaches for controlling bacterial growth, particularly through novel dynamic surfaces. In the last few years she has invented and continued to make groundbreaking contributions in the design and application of a new class of material coatings that show nearly complete repellence to substances of all kinds.

Joanna is the Amy Smith Berylson Professor of Material Sciences at Harvard John A. Paulson School of Engineering and Applied Sciences, a Professor of Chemistry and Chemical Biology in the Department of Chemistry and Chemical Biology, and Co-Director of the Kavli Institute for Bionano Science and Technology. She is elected to the National Academy of Sciences, American Academy of Arts and Sciences, American Philosophical Society, American Association for the Advancement of Science, National Academy of Engineering; and she is a Fellow of American Physical Society and Materials Research Society. Dr. Aizenberg received numerous awards from the American Chemical Society and Materials Research Society, including Fred Kavli Distinguished Lectureship in Nanoscience, Ronald Breslow Award for the Achievement in Biomimetic Chemistry, Arthur K. Doolittle Award in Polymeric Materials, ACS Industrial Innovation Award, and was recognized with two R&D 100 Awards for best innovations in 2012 and 2013 for the invention of a novel class of omniphobic materials and watermark ink technologies. In 2015 she received Harvard's most prestigious Ledlie Prize that is awarded for the most valuable contribution to science made by a Harvard scientist. Joanna served on the Board of Directors of the Materials Research Society, the Board on Physics and Astronomy of the National Academies, and the Advisory Board of Advanced Materials, Langmuir and Chemistry of Materials. She has authored ~200 publications and holds ~50 patents.

She received the B.S. degree in Chemistry in 1981 and the M.S. degree in Physical Chemistry in 1984 from Moscow State University, and the Ph.D. degree in Structural Biology from the Weizmann Institute of Science in 1996. She then went to Harvard University where she did postdoctoral research with George Whitesides on micro/nanofabrication and near-field optics.

William Gorman, Medical Device Quality and Regulatory Consultant

A technical professional with 30 years of medical device experience. Skilled in: ISO 13485 Certification, CE marking, FDA submissions, project management,

start-ups, product development, design control, quality systems, audits and regulatory interface. Certified lead auditor. A solid track record of bringing devices from concept to market. At PionEar William assists with developing strategy, provides technical support and prepares 510(k) submission.

Robert Cunningham, Business Advisor

Robert brings expertise in product development, grant and venture capital financing, and business development in numerous medical device and biotechnology markets and applications and has experience playing executive roles in companies commercializing robotic systems, filtration technologies for industrial and medical applications, and orthopedic and transfusion therapy products. Cunningham holds a B.S. in Biochemistry from the University of California at San Diego. He is a member of the Massachusetts Medical Device Industry Council, New England Healthcare Executives Network, and the Massachusetts Biotechnology Industry Council.

3. Executive summary

i. Clinical unmet need and solution

Acute otitis media, also known as an ear infection, and otitis media with effusion are the leading causes of healthcare visits worldwide, affecting >700M people each year and instigating considerable patient morbidity. Chronic ear infections are currently treated via the insertion of tympanostomy tubes (also commonly known as “ear tubes”) into the eardrum that help equalize the pressure of and drain fluids from the middle ear. Each year, nearly 700,000 children in the U.S. are treated with surgically implanted ear tubes rendering it one of the most common outpatient surgery under general anesthesia. However, ear tubes frequently suffer from complications, notably the occlusion of their lumen by cellular debris, pathogenic bacteria, earwax, blood and pus that then hinder drainage of fluids out of the middle ear as well as its proper ventilation. Various materials and design limitations also prevent efficient delivery of antibiotic solutions and can result in premature fall-out of the ear tubes, requiring further replacement surgeries under general or local anesthesia in up to 50% of patients, and leading to damage to the eardrum and hearing loss.

ii. Technology description and validation

The PionEar’s Tympanostomy Tube Technology, developed from a multi-institutional collaboration between bioengineers at the Aizenberg and Lewis Labs at the Wyss Institute, and ENT (Ear, Nose, Throat) surgeons at Mass Eye and Ear,

the top-ranked hospital in the nation for otolaryngology, harnesses bioinspired engineering principles to address the challenges of the currently available ear tubes. PionEar's technology provides three key benefits compared to state-of-the-art ear tubes, opening doors for an attractive ENT medical device market opportunity:

- *Optimal geometries and surface modifications* enabling an improved highly selective fluid flow through the tubes, allowing for a first-of-its-kind effective delivery of therapeutic drops into the middle ear,
- *Anti-biofouling materials* featuring suppressed adhesion of biofluids, cells, and bacterial films,
- *Optimal form factor and mechanical properties* that allow for minimizing the invasiveness of the surgical procedure and damage to the eardrum.

PionEar's technology exploits and builds on the unique fluid-transport properties of the novel ear tubes through combining optimized tube geometries with biocontamination-resistant materials. PionEar's novel materials have a "friction-free" surface that robustly resists biofouling from cellular and bacterial films and other contaminating biological fluids. Integrating PionEar's materials into tube with an intelligently optimized geometry allows for a selectively preferential, bidirectional flow of one or more liquids, e.g. therapeutic solution and middle ear discharge. For specific therapeutic solutions, the geometric parameters of the tube can be modularly tuned to significantly enhance the fluid transport.

We have reviewed well-established ear tube products produced by large medical device manufacturers (Olympus, Medtronic, Grace Medical, Anthony Products, Heinz Kurz, Adept Medical, Summit Medical). Commercial metal, silicone and fluoroplastic ear tubes are ineffective for preventing human cell and bacterial adhesion, causing clogging and premature extrusion, and do not address the limitations due to poor antibiotic drug transport into the middle ear. Our unique solution achieves all benefits simultaneously in one system: (a) anti-biofilm formation (b) anti-clogging and (c) enhanced antibiotic drop delivery. A particular advantage of technology is that it can reduce the need for revision surgery and can be customized and optimized for a host of various specific clinical indications. In summary, PionEar tubes can alleviate the highly prevalent issue of recurrent ear infections and downstream complications, and open up new avenues for the treatment of a broad spectrum of middle and inner ear diseases.

PionEar's team has validated the technology during the Phase I Wyss Validation Project supported by the grant at the Wyss Institute, and has secured the Phase II Grant for 2019-2020. The obtained results clearly demonstrate the high value and transformative potential of the PionEar's technology, and signify the de-risking of both in-vitro material design and in-vivo safety. The safety of PionEar tubes was

confirmed in in vivo studies in a chinchilla model at Mass Eye and Ear, and the efficacy studies with a CRO partner are ongoing.

iii. IP

The key aspects of the technology are the basis of one international patent application (PCT): Aizenberg J.; Black N. L.; Kozin E.; Kreder M. J.; Pavlichenko I.; Remenschneider A. "Designs for tympanostomy conduits or subannular ventilation conduits and other medical and fluidic conduits" (March 2019).

iv. Traction

To date the PionEar Technologies, Inc. has won several competitions: Grand Prize in Healthcare and Life Sciences Track of the Harvard President's Innovation Challenge 2018, Gold Prize of the MassChallenge Boston 2018 Competition, Grand Prize at the Collegiate Innovators Competition 2018 by the National Hall of Fame and USPTO, Audience Choice Grand Prize at Mass Innovation Nights 115's 5th Annual Female Founders Event 2018. PionEar's technology was also named Top 500 at Hello Tomorrow Global Challenge 2018 and top 10 at the Tech Planter Boston 2018. In addition, the team has been accepted to the Harvard Innovation Labs' Venture Incubation Program for four times in 2018-2019, and established presence online via the NECN Business TV Channel, Smithsonian, Bertarelli Foundation website, and Bostinno. The team has also participated as one of the Top 5 finalists in the highly-competitive MassBio MassConnect program in 2018, and was matched with a network of mentors and one MBA project manager to meet on a weekly basis and improve the FDA approval, commercialization, and customer adoption strategies. In 2019, the team was also accepted to the MassMedic Ignite 2019 program focusing on medical device innovation and entrepreneurship. In May 2019, PionEar Technologies was named "20 medical device startups you need to know" by Medical Design and Outsourcing magazine.

PionEar's team has confirmed the unmet need and market opportunity by surveying more than 100 stakeholders (parents, pediatricians, ENT surgeons, insurers, medical device distributors). Dr. Ida Pavlichenko has presented the technology to key opinion leaders (KOLs) at two major otolaryngology conferences in the US: AAO-HNS 2018 and ARO 2019, and has gained significant interest from several KOLs.

4. Deck pdf. attached.

5. <https://wyss.harvard.edu/technology/liquid-infused-tympanostomy-tubes/>,

6. PionEar Technologies, a startup company emerging from the Wyss Institute for Bioinspired Engineering, aims to advance the treatment of ear infections with minimally invasive ear tube implants that reduce biofouling and enable drug transport into the middle ear. The PionEar team is utilizing a novel technology from the Aizenberg lab at Harvard to develop a new generation of customizable ear tubes based on biocompatible materials that prevent cells, microbes, and biofluids from sticking to the surface, and provides a friction-free conduit for a more effective resolution of infection and targeted drug delivery to treat a broad spectrum of ear diseases.

7. We are seeking for an experienced MedTech or BioTech CEO to help facilitate fundraising and subsequent spinning out from the Harvard University for an early-stage medical device company with a de-risked technology and the first product in the pipeline that is currently in the 510k pre-submission phase. An ideal candidate should have fundraising experience both with angels and VCs, and, preferably, medical device commercialization experience and strategic partnership negotiation. The candidate should be willing to actively participate in fundraising in Fall 2019/Winter 2020. Part-time salary and equity compensation will be negotiated.