Laronix Pty Ltd.
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Medical Device Industry

Executive Leadership

Co-Founder/CEO:
Dr. Farzaneh Ahmadi
Co-Founder:
Mousa Ahmadi

Advisory Board
Mr. Ben Wright,
Business Advisor, AUS
Cicada Innovations

Professor Tomoki Toda,
Scientific Advisor
Nagoya University Japan
Google AI

Martin Krusin, Business Advisor, US
Senior Vice President of AzurRx BioPharma.

Aoifa Brogan, Regulatory and QMS advisor

Nancy Lincé,
FDA consultant

Rebecca Schaffler, Clinical advisor

Accelerator programs (completed)

CSIRO ON, Australia's Science and Technology Accelerator, 2020.

Entrepreneurship lab (Elab), New York's Most prominent medical device accelerator program 2020.

Finance
Funding Raised: $1,300,000
Sources:
A$45,000: F&F,
A$55,000: Grant,
A$660,000: Angels (SAFE), 2021
A$550,000: Australian Ministry of Industry (Grant), 2021

Finance Sought: $3,000,000
For voice cloning using AI, Mobile App development, CE registration, etc.

Executive Summary

Laronix is introducing Bionic Voice (Ava™) a breakthrough smart wearable, artificial voice box and mobile App for larynx amputees (laryngectomy patients). Our mission is to generate a natural sounding voice for these people and to transform the standard of care with our technology.

Company History

Laronix is a spin-out of a global pioneering research in natural voice synthesis for larynx amputees and garnered more than A$1.3 million in academic grants since 2016. Laronix's Bionic Voice box is recognized as a discovery that has changed voice prostheses technology worldwide[1] and is the winner of 50,000 A$ Australian Bionics Challenge Award in 2021 (see https://www.laronix.com/ for details).

Market Opportunity / Unmet Need

Laronix's core expertise is voice cloning (ultra-realistic deep fake voice) technology which is using artificial intelligence (AI) algorithms to mimic people's natural voice. This market is growing 30% annually and expected to reach A$2.4 billion in 2023. The voice prostheses subset of our market is growing 2.7% annually and expected to reach A$500 million in 2023 in developed countries (40% of the total available market).

Competition

The existing standard of care for generating voice after the loss of larynx is surgical. It has more than a 50% failure rate[2] and subjects the patients to severe infection hazards. The global market leader for the existing standard of care of voice prostheses is a company called ATOS Medical. In 2016, ATOS was acquired for A$1.4 billion deal[3] reaching a valuation of A$3 billion A$ in 2021[4]. Laronix is highly anticipated to replace the standard of care as we provide a quality better than the standard of care. The wearable design also protects the patient from bio-hazards.

Products/Services – Launched & Pipeline

Laronix's voice prosthesis generates a natural sounding voice for the patient. The prosthesis is non-invasive and driven by respiration. It also has an AI component similar to those used in digital assistant devices like the Google Home, that can be trained to reach a quality resembling the natural voice of the patient before the loss of their larynx. We have established the performance of our minimum viable prosthesis product (MVP) in clinical trials with 11 patients. Our larynx amputee participants comfortably talk with the device, generating an exceptionally high-quality voice while enjoying the product's non-invasive design.

Commercial / Technical Milestones

Laronix has received FDA registration for its Bionic Voice device as a battery powered electronic artificial voice box and an FDA Class I and 510k exempt device (Classification code ESE). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=715037&lpcd=ESE.
Laronix is now seeking TGA clearance in 2021 and will start initial USA/Australian sales in 2022.

Intellectual Property

Laronix has received an exclusive worldwide license to commercialize the Intellectual Property Rights (IP) from Western Sydney University through the Easy Access framework. We also have filed a PCT patent for our device's portfolio with a prominent law firm, Davies Collison Cave (DCC), in Australia with priority date of November 2020.

Financial Projections (Unaudited)

Laronix products and serviced includes Bionic Voice and our mobile Voice app as a software suit. Bionic Voice device is contract manufactured and is composed of an electronic prosthesis and its disposables, both typically covered by insurance. The electronic prosthesis is priced at $3000 per unit (77% gross margin) and disposables for $1370 per user per year (90% gross margin). The margins are expected to expand over time with scaled manufacturing leading to lower production costs at larger volumes. Our business model is a razor/razor blade model based on the one-time sale of the electronic prosthesis device and ongoing sales of disposables. This means that each year, we will sell these disposables (razor blades) to the new patients of that year and a cumulative sum of patients in the years before. Hence, our sales are expected to grow exponentially.
The mobile app has a subscription model of 30 $ per month and is only AI solution, enabling voice loss patients to speak over the phone or via Zoom with a natural quality voice. The revenues below are for a user base of 35,000$ APP users and 12,000 Bionic Voice users in 2027. Our projected revenue:

Year	2022	2023	2024*	2025*	2026*	2027*
Revenue	$ 0.05 M	$ 2.6 M	$10.2 M	$22.7 M	$ 49.4 M	$ 85.4 M
Gross Profit	$ 0 M	$ 0 M	$0.5 M	$6.7 M	$ 13.6 M	$ 32.9 M

- Bridging on Medicare for reimbursement

[1] https://www.westernsydney.edu.au/newscentre/news_centre/more_news_stories/discovery_to_alter_the_path_of_bionic_voice_research_worldwide
[2] Scherl, Claudia, et al. "Secondary Tracheoesophageal Puncture After Laryngectomy Increases Complications With Shunt and Voice Prosthesis." *The Laryngoscope* (2020).
[3] https://www.reuters.com/article/atos-medical-ma-pai/eqt-sells-atos-medical-sources-value-deal-at-850-mln-euros-idUSL8N18R3G8
[4] https://www.reuters.com/article/us-atos-medical-sale-idINKBN2EZ2C7