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Funding to Date:
Robertson Therapeutic Development Fund (RTDF) at Rockefeller University

- $70K, 2018-2019
- $250K, applying Jun 2019

Seeking $1M
to produce 500 clinical devices and hire two technical sales associates to install and train health care providers

Legal:
Incorporate July 2019

Patent 62/528,420 filed 2018, stimuli used in the test, held by Rockefeller University

Executive Summary:

Smell dysfunction is a reliable symptom of several health conditions with large economic impact including sinusitis and Alzheimer's disease, yet there is no quick reliable test for a patient's sense of smell. We developed a quick, cost-effective, and versatile test of olfactory function that can be administered using a digital diagnostic device.

Market Opportunities:

Currently, smell testing is rarely used by clinicians because available tests are labor-intensive and time-consuming. A quick, self-administered smell test will permit smell testing as part of the diagnostic battery for various conditions in which smell loss has been shown to improve diagnostic accuracy. For example:

Diagnostic tests of olfactory function in patients with nasal diseases such as sinusitis, nasal polyps, or a deviated septum will identify more patients visiting ear-nose-throat doctors that would profit from nasal surgeries like sinus surgeries and septoplasties. Currently, more than 500K nasal surgeries are performed every year in the US at a cost of approximately $5B. Assuming a cost of $15 per test, pre- and post-operative testing of smell function in this population is a 7.5M market.

Olfactory dysfunction is a very early, predictive symptom of Alzheimer's disease, which affects 5.7M Americans. More than 400 clinical trials for Alzheimer's are currently underway. With the average cost of an efficacy trial of $20M, these trials represent a cost of $8B. Olfactory testing improves specificity and sensitivity of predicting who will develop Alzheimer's and will improve targeted enrollment of patients likely to develop Alzheimer's, thereby reducing the total number of participants needed and the cost associated with identifying, recruiting, and enrolling participants.

Product:

Digital, app-controlled device to diagnose olfactory dysfunction in a clinical setting. The plan is to provide the device to health care providers at low or no cost and charge per test.

Jul 2019: proof-of-concept prototype financed by $70K RTDF grant

Jul 2020: production-ready prototype with normative data financed by $250K RTDF grant

July 2020: start of production and distribution of 500 clinical devices (50 to providers specializing in smell dysfunction, 100 to clinical Alzheimer trials, and 350 to providers of nasal surgeries). Financed by $1M in funding.

Commercial Milestones:

July 2019 upon incorporation:

- start IP negotiations with Rockefeller University
- start negotiating with hardware supplier about a strategic alliance.

Competition:

Currently only manual clinical tests of olfactory function exist. The SIT from *Sensonics* is a peel-and-sniff booklet in which smells have to be identified and the correct answers circled with a pen. Unlike our patented smell test, the SIT is influenced by odor-specific variability in sensitivity and depends on prior experience with the odors. Being a manual test, it takes almost twice as long as our test (13min vs. 7min) and does not allow for seamless integration into electronic medical records which results in additional time, labor, and cost for manual data entry.

Financial Projections:

Anticipated revenue: 2020: 150K (10K tests)
2022: 3M (200K tests) anticipated break-even
2025: 9M (600K tests)