

This Is What Success Looks Like

The National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program each year issues thousands of request for proposals (RFPs) offering small health technology firms and entrepreneurs an opportunity to turn broad concepts into original, marketable healthcare or medical technology solutions. In particular, the NIH SBIR program awards seed grants, \$225,000 in Phase I and \$1 million in Phase II, to small businesses for the development of health technologies that are novel, feasible, commercially viable and meet an unmet healthcare or medical need.

Below are three successful stories highlighting how these companies met the NIH SBIR program challenge and produced problem solving, lucrative healthcare solutions. The stories, more importantly, provide information on how the NIH SBIR's funding contributed to the growth of each company.

The three companies succeeded in the NIH SBIR program by (1) identifying a significant healthcare or medical problem that required a unique, marketable solution, (2) collecting market research and scientific information/data that supported the development of a novel health solution, (3) defining business strategy that focused on post-product development commercialization, and (4) forming a team of committed, experienced, knowledgeable individuals.



To learn more about how you and your company can become a NIH SBIR program success story with the current RFP releases, please contact Mr. Darrell Williams, at darrell@eighteenventures.com or (207) 347-1214.

Also, please visit Eighteen Ventures' website homepage, www.Eighteenventures.com, to download the following: Recently issued NIH SBIR program RFPs/new health technology development opportunities and Funding New Health Technology Development, which describes how win NIH SBIR funding.

A Spoon that Stabilizes Hand Tremors for Patients with Parkinson’s Disease and Essential Tremor

Lift Labs is a medical device company that creates stabilizing technologies to help people with Essential Tremor and Parkinson’s disease. Both Essential Tremor (ET) and Parkinson’s disease (PD) are neurological movement disorders that interfere with many aspects of a patient’s daily life including eating, drinking and writing. Essential Tremor affects around 10 million people in the United States alone and millions more are afflicted by tremors due to other neurological damage or dysfunction.

In 2010, Anupam Pathak, the Founder and CEO of Lift Labs (formerly known as Lynx Design), applied for his first NIH Phase I Small Business Innovation Research (SBIR) award that provided funding for a feasibility study of an Active Cancellation of Tremor (ACT) device. At that point, Pathak left his laboratory job and established a sole proprietorship, Lynx Design, where he worked by himself on the feasibility of a new technology for one year. His research results proved to be very promising and received additional Phase II SBIR funding in 2011 to continue the ACT product development through clinical research and additional R&D. Overall the NIH support was instrumental in accelerating all of the research and development efforts and enabling the commercialization of the product within three years.

In 2013, Lift Labs received a small private round of funding enabling it to launch its newly branded product Liftware™, a spoon that uses sensors to detect hand tremors and counteract them to minimize the spilling of food. “Eating can be more about being with people instead of worrying about spilling,” says Pathak. Depression due to frustration and social isolation are typical symptoms for ET and PD patients in particular. The product can help many people stay independent longer and regain their self-confidence in being able to lead better quality and socially active lives.

The initial launch generated a lot of interest online and the product demonstration videos received millions of views. This surge of online interest helped the product gain market traction and Lift Labs started to receive its first online orders. The product currently retails for around \$300, and the company has raised enough money through foundations and donations to give away a few hundred spoons to people who cannot afford them.

Lift Labs was acquired by Google in September 2014 and is being integrated into Google Life Sciences, which is part of Google X. The details of the deal remain closed, but Google Life Sciences hopes that the Liftware spoon will be the beginning of a long road that could potentially lead to other technologies.

Mobile Application to Improve Medication Adherence

Ai Cure Technologies was established in 2009 to develop webcam software solutions for mobile devices and other computing platforms that automate and reduce the cost of monitoring patient behavior and medication adherence. The company leaders set out to develop an artificial intelligence smartphone application that would visually confirm medication ingestion. In other words, it would help ensure the right patient takes the right medication at the right time.

Hospitalizations and poor health outcomes due to medication nonadherence cost the U.S. approximately \$290 billion each year. In addition, poor adherence prevents researchers from properly assessing a drug in clinical trials, which contributes to a high failure rate. Clinical trials can cost \$1 billion or more, and they most often fail because researchers cannot prove a therapy's effectiveness or safety. These pitfalls ultimately can be harmful to patient health and quality of life.

Although researchers already have several options for estimating adherence, such as pill counting and medication containers that record and track administration, these methods cannot confirm actual intake. Direct observation of patients is costly, invasive and impractical, and self-reporting of medication behaviors by patients can be imprecise and unreliable. The AiCure group devised the artificial intelligence adherence technology to address these translational barriers and provide a more efficient and accurate way to measure adherence.

AiCure, received a Small Business Innovation Research (SBIR) Phase I grant in 2011 from the National Center for Advancing Translational Sciences (NCATS) . With the Phase I grant, the AiCure team successfully demonstrated that the platform was technically feasible and able to confirm that patients have taken medication. Based on this success, NCATS awarded AiCure a Phase II SBIR award in 2013. This funding enabled validation of the technology against blood levels of medications and showed that the app improves adherence rates in schizophrenia and stroke patient populations.

After completing the SBIR program, the company's success included further NIH support, raising private capital funds and forming corporate strategic partnerships. The initial two SBIR awards led to additional non-SBIR NIH grants focused on studies involving substance abuse. The NIH SBIR funding support enabled the company to attract and leverage an additional \$12.25 million in financing from venture capital investors. Finally, the company entered into contracts with five of the top 12 global pharmaceutical companies to provide the adherence-monitoring app for clinical trials of experimental drugs.

Discharge Decision Support System (D2S2)

With SBIR funding from the National Institute of Nursing Research (NINR), RightCare Solutions, Inc produced a decision support system for Hospital discharge planning. The Discharge Decision Support System (D2S2) was developed to identify the right patients for post-acute care and get them the care they needed to prevent post discharge complications such as readmission.

Hospital discharge planning is a frequently occurring and expensive hospital care process done annually for more than 13 million Medicare beneficiaries. The process has multiple steps that require careful, comprehensive assessment to adequately determine patients' present needs, anticipate future needs, make appropriate referral decisions, and coordinate follow-up services. Although the volume of decisions for hospitalized older adults is high, there are no nationally recognized, empirically derived decision support tools in use to assist discharge planners and others in making these important decisions.

D2S2 enhances the referral decision making of hospital clinicians as they prepare patients for hospital discharge. The product improves identification of patients who would benefit from care after hospital discharge by providing expert advice and additional information about patients. When applied in clinical settings, the product had a predictive accuracy of 83% for identifying patients who should be referred for post-acute care.

A growing national concern regarding high readmission rates help boost D2S2 acceptance as a viable solution. In particular, the passage of the Patient Protection and Affordable Care Act (PPACA) in 2010 placed readmission as a top issue for US hospitals. PPACA's Hospital Readmission Reduction Program, specifically, tied 30-day readmissions directly to financial penalties, which meant the hospitals had to find ways to reduce to costs of and incidents of readmissions. This particular provision accelerated the commercial opportunity and paved the commercial need for solutions like D2S2.

RightCare licenses its proprietary software to hospitals and health systems to assess patients for post-acute care needs, determine risk of readmission, and coordinate patient discharges to high-quality post-acute care providers, with the ultimate goal of improving care transitions and health outcomes. The company also licenses its software to post-acute care providers, allowing them to save significant time and money in managing referrals from nearby hospitals by automating many of the burdensome administrative tasks involved in accepting referrals.

In 2015, Cardinal Health subsidiary naviHealth acquired RightCare Solutions.