



## From Concept to Commercialization

A look at one Southern California accelerator and two innovative medical breakthroughs poised to improve accuracy in continuous glucose monitoring and pinpoint risk factors following DCIS diagnosis.

By Sheryl Perez and Trudie Mitschang

According to Wikipedia, innovation is the creation of better or more effective products, processes, services, technologies or ideas that are readily available to markets, governments and society. It is often the latter part of this definition that is overlooked, as novel products and technologies are not always linked to a strategic path that can bring them to market. Capital is, of course, one of the necessary ingredients to help innovation on the path to commercialization, but it often isn't enough. There are strategic venture groups that not only invest in medical breakthrough technologies, but also function as accelerators to provide the many resources and strategic relationships necessary to bring these early-stage companies to market.

Roy Cosan, managing director, Fjord Ventures, says to create real value in today's marketplace, it is important to first maximize efficiencies. According to Cosan, Fjord does this by operating capital-efficient companies that can allocate a larger portion of their operating budget to development costs. This is enabled in part by sharing infrastructure expenses across multiple companies. "As an investment group and accelerator of medical technology, we always make sure to identify our strategic partners and the go-to-market approach before investing in the development of novel technologies that include pharmaceuticals, devices and diagnostics," Cosan says.

The Fjord model, founded by managing partner Olav Bergheim, focuses on novel, disruptive medical concepts that have been created through participation of leading academic labs, medical industry thought leaders, entrepreneurs, multinational corporations and experienced management.

### Improved Monitoring Device for Diabetics

One of Fjord Ventures' portfolio companies, Metronom Health, has pioneered a smart sensing platform to continuously monitor glucose in diabetics. Metronom founder and CSO Troy Bremer explains his motivation for developing the device: "I was frustrated by the technology gap between what I was working with in the defense industry and the tools available to help my wife manage her disease — she is a type 1 diabetic, and there were no CGMs [continuous glucose monitors] on the market then." Though CGMs are now readily available, Dr. Bremer experiences firsthand the inadequacies inherent in such systems. "I continue to watch my wife struggle with devices that are helpful but still have limited utility," he states. "The monitors she uses have a false positive rate in the range of 30 to 40 percent. This uncertainty needs to be eliminated to allow patients to easily and effectively manage their disease."

Working as an aerospace engineer, Bremer was used to dealing

with complex challenges and left his career to pursue a PhD under the guidance of the world's leading expert in glucose biosensing at the University of California, San Diego. After graduating, Bremer and his colleague, professor Elliot Botvinick threw themselves into furthering the development of what they now refer to as a real-time smart glucose sensor.

## Understanding Diabetes

Diabetes is the most rapidly growing chronic disease of our time. The downstream consequences of not properly monitoring and treating diabetes are staggering. As the leading cause of new blindness and kidney disease, it also contributes to the nation's No. 1 killer, cardiovascular disease. In addition, the cost of treating diabetes is staggering.<sup>1</sup> According to the American Diabetes Association, the annual cost of diabetes in medical expenses and lost productivity was \$174 billion in 2007.<sup>2</sup>

Metronom's CGM has the potential to significantly impact the ability for patients and their caregivers to make meaningful real-time treatment decisions by having a smart device that provides accurate data. The lifestyle/human factor of the device that must be worn by a diabetic has also been improved with a form factor that is easier to insert and more pliant and comfortable to wear. Further, information can be relayed to a patient's smart phone, computer or other device for easier reading. The economic impact for a patient who is able to accurately monitor their glucose and treat surges and declines quickly is also significant when you consider the costs of treating the far more pervasive diseases that diabetes can lead to.

Looking ahead, the growth path of Metronom's technology holds tremendous promise as well. "While there is significant value in this CGM as a stand-alone product, what is especially exciting is the integration of this continuous glucose monitor with an insulin pump to eventually create an artificial pancreas with the capability of automatically pumping the correct amount of insulin based on each patient's variables such as height, weight and glucose level, without the patient or provider's intervention," says Cosan, chief executive officer, Metronom. The idea of an artificial pancreas is not new, but no current CGM in the market has shown the level of accuracy required to gain FDA approval. Metronom Health's CGM may be the missing link.

## Breast Cancer Breakthrough

Another innovative company in the Fjord portfolio is Prelude Corp., which is currently pioneering the PreludePx DCIS test for patients diagnosed with ductal carcinoma in situ (DCIS), the most common type of noninvasive breast cancer.

According to The American Cancer Society, the majority of patients diagnosed with DCIS today undergo lumpectomy followed by radiation treatment. Radiation is typically given as a precautionary step to minimize the odds of the cancer

recurring. Unfortunately, a significant number of patients who receive radiation and all of its health-compromising side effects may have been able to avoid treatment if there were a more accurate way to assess individual risk factors. The Prelude test promises predictive power beyond the traditional clinicopathologic features to more accurately stratify patient risk of recurrence following DCIS diagnosis. The test will build on previously validated molecular markers — assayed by immunohistochemistry (IHC) in the tumor tissue and established clinicopathologic risk factors.

"We believe this prognostic will help physicians better balance treatment risk with patient benefit to prevent unnecessary overtreatment in low-risk patients and identify high-risk patients otherwise missed by traditional assessment," says Cosan, who also acts as chief executive officer, Prelude Corp.

Currently, despite the frequent use of adjuvant radiotherapy to treat DCIS, it only prevents recurrence in an estimated 5 percent to 10 percent of lumpectomy patients, and its ability to reduce breast cancer-associated mortality is likely less than 1 percent. "Tens of thousands of patients per year receive unnecessary radiation treatments contributing to morbidity and increased healthcare costs," says Cosan.

Cosan explains that accurately identifying patients by risk profile will enable treatment standardization and achieve higher-quality/lower-cost care. While the economic savings are significant, when it comes to deferring radiation treatment, the ability to minimize the human cost is even more significant. With the Prelude test, patients with a low-risk diagnosis may opt to decline radiation treatment entirely; their physician would then manage the ongoing standards of care through annual follow-up exams, mammograms and MRIs.

The PreludePx DCIS test is approximately two years away from market launch and is currently moving into the clinical trial phase.

## Closing the Gap

With so much to gain in human and economic value, it is not always clear why some of the most promising technologies remain dormant or are allowed to fall through the cracks. Many just run out of money. The secret may lie in the comprehensive understanding and strategic engineering that medical technology accelerators such as Fjord Ventures provide. ❖

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