



Identifying the next big thing in biotechnology is Celdara Medical's specialty.

# CELDARA MEDICAL, LLC

How much good could you do with \$30 billion dollars and the smartest people in the world? That is the question that the founders of Celdara Medical asked themselves when beginning the company in 2008. Each year, the National Institutes of Health allocates \$30 billion to the best and brightest researchers in the US, which results in an unparalleled source of innovation. The SBIR/STTR program then helps start-ups like Celdara perform the development needed to bring these new and innovative products to the clinic.

## PHASE III SUCCESS

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## AGENCIES

HHS (NIH)

## SNAPSHOT

The company is currently working with more than 30 academic institutions representing over \$5B in annual R&D spending to identify, vet, and advance the most clinically promising therapeutics and diagnostics.

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Using a pipeline/portfolio strategy, Celdara works to identify discoveries of exceptional value at the earliest stages and moves them toward the market and into high-potential medical companies. Transforming research into real solutions for real problems is what Celdara Medical aims to achieve by accelerating science to improve human health.

"There is a bottleneck in the biotechnology innovation ecosystem and we wanted to help innovators overcome it," said Jake Reder, CEO, Cofounder, and Director of Celdara. The need that company founders saw was a way to move outstanding technologies from university laboratories into the commercial sector. This need was addressed by setting up Celdara to act as a unique variation of a technology incubator/accelerator. SBIR plays a critical role in the model. SBIR funding is essential for the development of early stage, high-risk, high-reward therapeutics, and it is essential to Celdara's business. In January 2015 Celdara spun out and sold "OnCyte, LLC," to Cardio3 Biosciences (now Celyad, NASDAQ: CYAD) for \$490M in cash, stock, and milestones, plus royalties on sales. OnCyte is built around a set of SBIR-funded cellular therapies, originally identified at Dartmouth Medical School, and built into a clinical-stage division within Celdara Medical. Celyad is now planning multiple clinical trials to advance the lead candidate into multiple sites and oncology indications, and both companies continue to collaborate on next-generation therapies.

"SBIR helps to mitigate risk – it helps to start with a low risk financial plan and at the earliest stages in an industry like biotech you need access to capital that can accept high levels of risk. It's a long path to liquidity, and like predicting the future, it's hard to pick winners," said Reder. SBIR funding has allowed the company to work at a stage of development that would otherwise be avoided – and if the early stage is avoided, it is to the detriment of everything else downstream, including new marketed therapies and ultimately, patients. The impact of SBIR funding was realized early in the company's life. Eleven months after the

company was founded, it received an SBIR award. Thanks to its Phase I and Phase II SBIR awards the company was able to achieve nine key milestones including 100% survival and 100% durable protection against tumor re-challenge in murine models of cancer and initiation of a Phase 1 clinical trial, which is currently ongoing at the Dana-Farber Cancer Institute. Celdara now has fourteen full-time and 6 part-time employees, as well as dozens of consultants and contractors, figures that do not include Celyad or OnCyte. In 2011 Celdara helped to establish an affiliate, Virtici LLC, in Seattle, which is running independent programs in additional areas, including metabolic diseases. Most recently the company opened an office in New York City to expand its network of innovators.

“There are many more assets out there than anyone knows about, but they aren’t making it to the clinic for a variety of very good, and very addressable, reasons. Biotech is tough, it is very high risk, there are issues of cash flow, and it takes a long time to get an innovation into the market,” said Reder. One way the company measures success is by risk-adjusted “quality-adjusted life-years” (QALYs) created. Its short-term goals include continuing to increase its impact by identifying innovative cures and therapies for disease. To identify these Programs, Celdara assesses approximately 500 assets each year by looking at the invention, inventors, IP, market potential, regulatory pathway, competition, standards of care, and other factors. Utilizing a portfolio approach and developing a diverse set of potential solutions mitigates risk for Celdara.

“We look closely at the data: was the appropriate animal model used, was it tested against a standard of care, was it blinded? We also consider the medical need: exactly how unmet is it, and what will that need look like in 10 years?” added Reder. These are the types of questions that Celdara uses as they target new solutions. The company’s long-term goal goes above and beyond QALYs generated within Celdara - the company hopes to improve how innovations enter the market by improving the overall biotechnology innovation ecosystem.

Reder’s advice to a company starting out is, “Be childlike – relearn how to really ask questions, and then ask everyone who can lend a perspective. There’s no stupid question. Talk to the experts, talk to their friends, talk to their rivals. When developing your business model, look at it as a hypothesis and apply the scientific method to each part of your process.” The results are seen in Celdara’s ability to engage both industry and academia. The company is currently working with more than 30 academic institutions representing over \$5B in annual R&D spending to identify, vet, and advance the most clinically promising therapeutics and diagnostics. SBIR funding has allowed Celdara to advance these technologies into the clinic and the market, and to build core competencies in key areas from pipeline management to regulatory affairs to preclinical development.



Celdara Medical helps innovators bring next-generation biotechnologies to market.