STANFORD
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RAISING FUNDS FOR SMALL MARKET OPPORTUNITIES THAT ADDRESS BIG NEEDS

"We first had to convince ourselves that a simple solution could work to prove that it would not have a high development cost or high regulatory risk, allowing us to build the product efficiently. Then we had to get the right people around the table to make it happen."
-- Eric Chehab, Co-founder and former CEO of Novonate

Background

When Eric Chehab was a graduate student pursuing his PhD in bioengineering at Stanford University, he enrolled in Stanford Biodesign Innovation course, a two-quarter graduate-level class focused on health technology innovation. The class assembles multidisciplinary teams of graduate students to identify unmet health-related needs, invent new technologies to address them and map the way forward to bring their solutions into patient care. The high-energy, project-based course attracts students across campus with a passion for entrepreneurship and a commitment to using technology to improve healthcare.

Chehab was assigned to a team that included medical student Carl Dambkowski. Their focus was on addressing important unmet needs related to bloodstream infections contracted in hospital settings. The team launched a multi-pronged research effort to better understand the problems linked to these potentially deadly infections. "We picked six areas of treatment involving central venous catheters, which are often linked to bloodstream infections. Then we dove into medical literature, public health information, and other online resources to better understand the problem areas," said Chehab. They were intrigued and troubled when they learned that, although pediatric patients require catheters far less often than adults, they acquire catheter-related infections at a rate that is five times higher.

Narrowing their focus to pediatrics, the team quickly learned that umbilical cord catheters are central lines that provide nutrients and medication to low-birthweight newborns but come with an especially high infection rate. "When we started researching how umbilical cord catheters were secured, we saw that the mechanism being used to hold them in place on tiny newborns was a 'bridge' the nurses would make out of surgical tape. It didn't look like the sleek, sterile devices protecting and supporting central line catheters in adults," recalled Dambkowski.

Further research and interviews with nurses and doctors validated the need for a better solution for neonates in intensive care. The overall market size was small – up to 300,000 newborns receive umbilical cord catheters each year in the US – but the need was compelling, with an abnormally high percentage of those babies acquiring a costly and dangerous infection and up to 1,000 babies a year dying as a result. "All for a condition that is largely preventable," Dambkowski emphasized. Upon researching the need further, the team identified a secondary complication with an even higher occurrence rate: umbilical catheter migration, which can occur in 40percent of patients.

The team committed to inventing a solution. Key design challenges included the umbilical cord dying naturally, so it must remain open to the air. Moreover, unlike an adult catheter, in which the central line is placed flush against the skin, the umbilical cord catheter line rises from the stump perpendicularly. They

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addressed these and other issues with LifeBubble. This small, flexible, dome-shaped product can be adhered to the baby's skin to secure the catheter in place while protecting the umbilical area from bacteria.

Although the device offered great promise, the team had other academic obligations to fulfill and temporarily put its project on hold when the class ended. However, about a year later, they were still preoccupied by the unmet need. Driven by a desire to help vulnerable newborns and their families, they decided to pursue the project in earnest.

Combining a Lean Approach with Non-Dilutive Funding

A key issue was how they would raise the money they needed for the development, testing, and eventual commercialization of LifeBubble in a pediatric market that was too small to attract traditional venture capital investment. “We knew from the get-go, even before we started the company, that funding would be challenging,” remembered Chehab. Based on the work completed to date, they realized that because the product was technically simple and its use was relatively low risk, they could take it forward using a lean approach. “Because this was developed at Stanford, we had virtually a zero burn rate while we were working within the university, which was great,” he continued. “Since Stanford owned the IP anyway [which is typical for projects initiated as part of a university course or research program], we could leverage university resources across campus, at little or no cost, to make substantial progress.”

However, as the project progressed, some important activities in their development plan would require funding to complete. In particular, they needed to generate benchtop data to convince users – and future funders – to support their work. They decided to pursue non-dilutive funding sources. Dambkowski brought the project to the attention of James Wall, a pediatric surgeon and the assistant director of the Stanford Biodesign Innovation Fellowship program. With Wall’s help, Dambkowski and Chehab secured a Stanford-based pre-seed grant (via the Stanford-Coulter Translational Research Grant program) for just under $100,000 that allowed them to recruit new team members, including Ross Venook and Eric Kramer. This award provided the team with enough capital to complete a series of studies that would generate essential data, as well as input to help them refine and improve LifeBubble’s design, including biologic testing to measure protection from bacterial contamination, mechanical testing to assess stability, and usability testing to get feedback from the NICU nurses who would be the eventual end-users of the product.

“The user feedback [was] especially valuable,” said Dambkowski. “While physicians like the idea of LifeBubble, the NICU nurses are the ones placing the device and working with it throughout the course of care. We learned that, in order for them to want to use it, it has to be quicker and easier than existing solutions and not disrupt their established workflow." The nurses introduced other design requirements as well. "For example, we initially wanted to make it rigid to maximize stability, but the nurses were extremely uncomfortable with that," Chehab noted. “Babies are soft and delicate, so whatever you put on them has to be soft and delicate too.”

In parallel with their lean development activities, the team continued to seek non-dilutive grant funding after they formally spun out of Stanford and formed the company they dubbed Novonate. Shortly thereafter, they applied for and won a $250,000 SBIR grant from the National Science Foundation (NSF). They also tapped into pediatric device consortia across the country, which are groups funded by the FDA to support product development in pediatrics and catalyze early-stage start-ups in the space. The team received one grant a year for four years from these consortia, each ranging between $25,000 and $50,000. These grants helped propel the team forward and were foundational to Novonate’s early

success. “The dollar amounts may seem small but ultimately moved the needle and funded the specific things we knew we needed to do before spinning a company out of the university,” Chehab stated. He noted, however, that grant writing requires skill to do well. Accordingly, the team hired a grant consultant to assist them collaboratively in preparing their subsequent applications. Chehab's primary advice when it comes to preparing grant materials was "…to pretend everyone reading your grant is doing it in the middle of the night with no sleep and four cups of coffee behind them. If they cannot understand it, you need to improve it."

Raising Funds to Form a Company and Spin Out of the University

The fact that Novonate made so much progress before translating their work out of Stanford and finding investors put them in an advantageous position. "We weren’t completely desperate for money at that point," said Chehab, so the team could take their time in finding the right investors to provide them with the money they would need to launch a company and bring the product to market. Through networking and diligent research, “We found a couple of VC investors with whom Novonate resonated – the opportunity, the path, and the story. Their small fund size and potential investment size made sense for our needs and theirs.”

Ultimately, Novonate did not raise money in the usual stages. They did a pre-seed round, followed by a “Series Seed” (which is similar to a Series A but leverages a less intricate provisions to enable a less complicated deal). This was followed by an extension due to Covid and then a bridge round involving SAFEs from angel investors. “SAFE stands for Simple Agreement for Future Equity, which usually stands up to its name. SAFEs are simpler than convertible notes and more company friendly. It's a four-page document, so there's less to negotiate,” Chehab said. “The other thing with SAFEs is that each agreement closes on its own. Unlike an equity round, where you need commitments from everyone and then add everything up and go through a rat race to close all at once, SAFEs (like convertible notes) can be closed individually.”

The company’s investors included Medical Technology Venture Partners, a traditional venture firm with a small fund and Springhood Ventures, a mission-driven pediatric venture capital group. MedTech Ventures, said Chehab, was a good fit because “we were a small start-up company focused on a small market, and they were a small venture capital group with their first fund. They wanted a diverse portfolio in all early stage medtech. So, they invested in larger start-ups and co-led some larger Series As but still invested in us. They were truly our primary investors for the life of the company." Novonate raised approximately 2 million dollars from investors from the project's inception to its acquisition by Laborie Medical Technologies

Advice for Working in a Small Market

Chehab underscored the importance of non-dilutive funding in Novonate’s journey. Because the company does not have to pay back the funds or issue equity in exchange for the money, it is particularly beneficial in the early stages of a project when valuing the technology/company is challenging. Chehab also found it to be ideally suited to a project focused on a small market. “Things often cost more and take more time than expected,” he said, “so you must be prepared. In spaces like healthcare, medical devices, and underserved markets like pediatrics, there are opportunities for non-dilutive funding that you absolutely should take advantage of.” The team identified these non-dilutive funding opportunities through networking with other pediatric start-up founders, the pediatric device consortia they joined, and accelerators such as StartX.

Regarding funding, in terms of the amount a company must raise, Chehab encouraged other innovators to plan their commercial strategy carefully. “There is a great deal of talk about needing to be capital efficient when developing a product for a small market, and that makes sense,” he said. “But I learned that there’s a renewed challenge at the commercial stage that doesn’t get talked about as much. You have to figure out how to sell your product and good sales reps are not affordable. Remember that you must fund the commercialization portion, too. Whether you are planning to find strategic partners or distributors or build your own sales force, commercial strategy must be proactively thought through and budgeted for.”

Finally, on an inspirational note, Chehab underscored the benefits of working in a small market. “Typically, in pediatrics, there are not many competitors to worry about and there are many ‘low-hanging fruit’ opportunities,” he stated. “Because a small market has been neglected and underserved, it can be compelling in many other ways. Also, the people who work in these small markets often want to band together and support each other, so there is a tight-knit community of pediatric medical device innovators. Finally, it simply feels meaningful to help babies in the NICU.” To date, LifeBubble has been placed on over 3,000 babies to secure and protect their umbilical catheters.

Key Insights

- A lean, capital-efficient development strategy is fundamental to pursuing a small market.
- Non-dilutive funding can play a substantial role in helping derisk small market projects.
- Grant writing skills are valuable for securing non-dilutive funding and should be developed or outsourced to make the team competitive.
- Innovators must plan their funding to support their commercial strategy in addition to their R&D strategy in order to successfully implement their innovation.