FUTURE FORWARD

HEALTH INNOVATORS LAUNCH INVENTIONS PROMPTED BY THE PANDEMIC

Venture Partners at CU Boulder funded a saliva-based infection test developed by Darwin Biosciences.

BY JEANNE McADARA, PH.D.

Throughout human history, even the greatest threats to human life and wellbeing have spurred innovation, creativity, and a heroic drive to overcome the challenge of the moment and secure a safer future. Faced with the sudden, urgent call of the COVID-19 pandemic, members of Colorado's life sciences community stepped up to save lives, adapt to the unanticipated burdens on our healthcare workers and systems, and, ultimately, curb the impact of COVID-19 on global public health. The impact of these breakthroughs, a few of which are shared below, are sure to last long beyond this pandemic.

Darwin Biosciences Starts Up and Makes a Difference

It was early March 2020. Nicholas Myerson, Ph.D., had just co-founded a new company to develop a new diagnostic technology with Sara Sawyer, Ph.D., a Professor at the University of Colorado Boulder's BioFrontiers Institute and the Department of Molecular, Cellular, and Developmental Biology, and two other colleagues.

"I'd been working with Sara as a postdoc, and our group had developed this novel method for detecting the body's earliest responses to infection, before a patient feels sick," says Myerson. "The advice we heard was, 'if you think you have a great idea, start a company to make it a reality.'"

Under the stewardship of Venture Partners at CU Boulder, Myerson, Sawyer, and their partners did just that, founding Darwin Biosciences (Boulder) to develop the Sick Stick, a disease-agnostic, saliva-based test to detect generalized onset of infection.

"And two weeks later, the country shut down," says Myerson, now Darwin's CEO. "We faced the prospect that funding would dry up. At that point, a two-week-old biotech company didn't seem like such a great idea." Shock turned into action. Myerson and his co-founders quickly saw an unmet need that Darwin could solve. "There was a huge shortage of COVID-19 testing capability, and results were taking a week," recalls Myerson. "Meanwhile, people were unknowingly becoming infected and spreading it in the community. Our test is easy to perform without complicated laboratory space and we get an answer in 40 minutes."

With support and seed money from Venture Partners at CU Boulder and CU's New Venture Challenge Award, they added a COVID-19 specific component to their test and created a turnkey solution, COVLAB, that was adopted by CU Boulder for a screening initiative. CU Boulder used it to test tens of thousands of students for the virus over the course of the year.

Myerson credits the support of Venture Partners at CU Boulder, the Rockies Venture Club's Hyper Accelerator program, and the broader life sciences ecosystem for his team's success in bringing the effort online rapidly under such high-pressure circumstances.

Brynmor Rees, the Assistant Vice Chancellor for Research & Innovation and a Managing Director of Venture Partners at CU Boulder

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– BRYNMOOR REES, ASSISTANT VICE CHANCELLOR FOR RESEARCH & INNOVATION CU BOULDER

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says, "What we learned out of this—and Darwin Biosciences is a good example—is that innovations like vaccines and diagnostics can be accelerated to market when the urgency is clear. Coming out of this year, we have greater public understanding of how pandemics work, better public health surveillance systems, and more capital resources. This won't be the last pandemic; the question is, will we be more prepared for the next one?"

UCHealth Builds an Infrastructure of Preparedness

As COVID-19 threatened to overwhelm healthcare capacity all over the nation and the globe, an enormous challenge for hospital and healthcare systems emerged—how to suddenly move almost all non-emergent patients to remote care.

That was no small task, according to Kimberly Muller, Executive Director at CU Innovations (University of Colorado Anschutz Medical Campus, Aurora). "UCHealth is a 12-hospital system spread across seven states. And when March hit, we had to go from full capacity to a total shut down. In 48 hours, we had to start delivering care to patients who couldn't come in person."

Richard Zane, M.D., is a Professor and the Chair of the Department of Emergency Medicine at CU School of Medicine and the Chief Innovation Officer for UCHealth. He says that UCHealth's forward-thinking culture helped the system successfully navigate the abrupt changes.

UCHealth's pre-pandemic investments created new ways to care for patients when and where they needed it. Alternatives to in-person visits included electronic communication, texting, and telehealth.

"We use technology deliberately and judiciously to make care seamless for the patient and the provider, whether it is in person or not in person, synchronous or asynchronous," says Zane. They wanted every patient—even those being monitored remotely for serious chronic conditions like diabetes, heart failure, asthma, or emphysema—to have the same relationship with their care team no matter where they were.

As part of this effort, the organization had begun a directed effort to develop and implement a robust, seamless, and intuitive electronic health record (EHR) that would facilitate and enhance provider workflows and the patient experience.

"All of the infrastructure we had put in place allowed us to scale up very rapidly," says Zane. "We had to add workstations, but we didn't have to implement a single new process, device, or technology that we didn't already have in place."

It was a massive transformation in real time. "We went from a few hundred telehealth visits per day before pandemic restrictions began, to thousands per day at the peak," says Zane. "But we were able to care for our patients by offering them an alternative to coming in that was, in many cases, just as good."

Zane believes that the lessons learned and changes made during the pandemic will have a lasting effect on how UCHealth delivers care. "This has been what I call one of those 'never go back' events," he says. "As in, I doubt we will go backwards from using remote care and virtual visits when the patient and the provider both feel it's appropriate to the specific situation."

CSU Focuses on Disease Readiness

"COVID-19 is the virus we have to solve today, and it will likely be with us for a long time," but it won't be the last, according to Raymond Goodrich Ph.D., Executive Director of the Infectious Disease Research Center and Professor in the Department of Microbiology Immunology, and Pathology at Colorado State University (Fort Collins).

Goodrich currently heads the effort to develop a process for rapid vaccine production called SolaVAX™. Using this process, pathogenic virions are treated with riboflavin which, when exposed to UV light, acts as an "endogenous photosensitizer." Unlike standard chemical inactivation processes, UV-activated riboflavin selectively targets nucleic acids while leaving proteins and other macromolecules intact, with native conformations. Thus, SolaVAX renders viruses incapable of replication, but able to present a native set of antigens to the body's immune system. An advantage of this approach, says Goodrich, is that the resulting vaccines display a diverse array of viral immunogens rather than a single, isolated protein fragment, giving the body more options for response.

Funding from BARDA and the NIH supports CSU's work to develop the SolaVAX® vaccine.

Just before COVID-19 began sweeping the globe, Goodrich's team at CSU was pursuing international collaborations to study the utility of SolaVAX for creating a vaccine against African swine fever. This livestock disease wreaks havoc on the nutritional and economic wellbeing of the developing world's populations. The collaboration had just produced its first batch of test vaccines when the pandemic changed everything. Given the circumstances, the team pivoted to join the global fight against COVID-19.

Goodrich and his CSU colleagues developed a virus-sensitive hamster model for preclinical testing, characterized the immune response to the virus and to various candidate vaccines, investigated the nature of the modifications being generated, and tracked responses to viral variants. Results to date have been encouraging.

"We've been very fortunate to receive generous funding from BARDA and the NIH," says Goodrich. "We have reached key preclinical milestones and are now working toward an IND application and a Phase I clinical trial, using cGMP material produced at CSU's BioMARC contract development and manufacturing facility."

Goodrich says that there will always be a need to innovate and develop novel approaches to disease prevention. He points out that the mRNA and adenovirus vaccines at the forefront of the COVID-19 effort didn't appear out of nowhere; the methods behind them had been developed in response to earlier threats, such as Ebola, Dengue fever, and Zika virus. Groundwork there enabled their rapid deployment against COVID-19.

"We live in a world in which the dynamics for agriculture, food distribution, travel, migration, and population growth make it ever easier for diseases like COVID-19 to emerge and affect human populations," says Goodrich. "SolaVAX is the next example of an emerging technology platform—developed in response to today's threats—that will help solve new ones as they emerge in the future."

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