One road out of ‘the Valley of Death’

Rosibel Ochoa, Geert Schmid-Schonbein & John Rodenrys

Would you be surprised if a researcher at a top U.S. university discovered a breakthrough for a medical problem that kills 215,000 people a year but couldn’t find funding to commercialize the discovery? You wouldn’t if you’d ever heard of the “Valley of Death.”

The Valley of Death represents the funding drought that startup and emerging companies face after a discovery is found but before they can find funding to help them move the company off the starting blocks. While Congress and the Obama administration continue their quest to find the silver bullet that will spark small-business job creation, universities are developing “proof of concept” centers that help startup companies survive the Valley of Death.

One such researcher who found his discovery stuck in the valley was Geert Schmid-Schonbein, director of the Microcirculation Lab at UC San Diego. Over a decade ago, Schmid-Schonbein discovered a treatment for multi-organ failure as a result of septic shock, using a drug already approved in the U.S. for other purposes. Sepsis is an unmet medical need causing 215,000 deaths a year in the U.S. and an in-hospital fatality rate of over 30 percent. In 2007 alone, U.S. hospitals spent over $38 billion fighting sepsis.

Although the need for a treatment breakthrough for sepsis was great, Schmid-Schonbein struggled to find funding to translate his discovery into a commercial product that hospitals could use. In 2006, he faced a funding roadblock. He had three choices: obtain additional government funding; find a venture capital firm interested in the discovery; or find “angel investors” to continue commercialization. Because the research was too early stage or not basic research, the government was not interested, leaving Schmid-Schonbein to seek private capital. But how does a scientist cross over into the complex world of private capital?

Fortunately, Schmid-Schonbein’s own university, UCSD, hosts the renowned William J. von Liebig Center for Entrepreneurism and Technology Advancement, whose mission is to accelerate innovation and facilitate interaction between academia and industry. The grant kept the research going while more capital was found. Center director Rosibel Ochoa arranged a meeting between Steve Flaim, a von Liebig adviser, Schmid-Schonbein and John Rodenrys of Leading Ventures, a product development company that invests in very early stage technology and is entirely funded by private accredited investors. Rodenrys was impressed by the discovery and worked to commercialize the technology.

The long-term studies were successful and showed significantly increased survival rates in animals. But successful navigation through the Valley of Death requires both a breakthrough technology and enough capital to support the technology all the way through. Unfortunately, funding from the private investors disappeared and capital became difficult to obtain. Leading’s approaches to venture capital firms were not successful, as the firms had moved to less-risky, “later stage” deals. Now the “perfect storm” existed – private capital, governmental sources, and institutional sources had all exited the market.

The Valley of Death roller coaster took another turn for the best as both the Navy Medical Center San Diego and the Department of Veteran Affairs’ San Diego Office found the research promising. Each sought funding for further studies, which took nearly two years to approve. The approval time could have been longer if the medication was not already approved.

The long wait in the U.S. was a sharp contrast to the experience in Taiwan. While Schmid-Schonbein was in Taipei teaching surgeons how to use the treatment in severely ill patients, the surgeons admitted a patient in serious septic shock. After exhausting conventional therapies, the surgeons concluded death was imminent. After obtaining consent, they tried the
treatment. The patient quickly improved, was released and is alive today. Since the visit, the Taipei hospital has treated 13 severely ill patients, with 11 surviving. If Taipei can implement a new treatment quickly, why are U.S. product development times so lengthy?

Several reasons are apparent: U.S. hospitals are afraid to take on risk because of lawsuits; regulatory reviews are longer; raising early-stage capital remains a difficult challenge; the federal government has been slow to fund Valley of Death therapies.

On Oct. 18, the authors will be on Capitol Hill in Washington, D.C., presenting at CONNECT’s Innovation 101 Hill Briefing, sharing our story while discussing what the government’s leaders can do to help more discoveries turn into commercial successes that create jobs. We will also discuss the need for reauthorization of certain federal research programs, the Canadian research and development tax credits, legislation to allow private-sector funding of proof of concept centers, and streamlining the regulatory process without weakening it. As the Valley of Death shrinks, patients will benefit.

Ochoa is executive director of UCSD’s von Liebig Center for Entrepreneurism and Technology Advancement. Schmid-Schonbein is distinguished professor and director of the Microcirculation Laboratory in the UCSD Department of Bioengineering. Rodenrys is senior managing director of Leading Ventures, a San Diego venture capital firm, and CEO of InflammaGen Therapeutics.

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