THE PATH TO COMMERCIALIZATION

Common themes help Colorado companies achieve success

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it down for coffee with your average Colorado bioscience insider, and inevitably the discussion will turn to the industry cluster’s progress since 2003. That is the year the Governor’s office released what is now known affectionately as “the Battelle Report.” Most agree that the flurry of activity following that report has spurred immensely positive and lasting changes in the state. However, the prevailing view also holds that Colorado’s relatively young industry cluster remains start-up heavy, and that companies still have to leave the state in search of the funding and partnerships they need to get them to the next stage.

Despite that view, ample evidence suggests that Colorado bioscience is approaching a new milestone in its evolution. With an increasing number of homegrown product approvals and commercial successes, more companies are demonstrating that it is possible to successfully navigate the corporate life cycle from concept to commercialization without leaving the state.

**Balancing diversity and focus**

At first it can be hard to identify a common thread to explain the success behind this eclectic collection of medical device, pharmaceutical and biotechnology companies. But look deeper, and certain patterns emerge. Development of a platform technology with the potential for wide-ranging applications is one example—many companies cite a commitment to focused product diversification as a critical factor both to their commercial success and, ultimately, to their ability to remain independent.

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A prominent example is TOLMAR, Inc., a fully integrated pharmaceutical company headquartered in Fort Collins. Although TOLMAR took its current form in 2007, its roots go back to 1990, when its predecessor, Atrix Laboratories, was founded around a vision of developing and commercializing pharmaceutical products in dentistry. Within a few years, the company’s leaders began to appreciate that they had developed something more fundamentally important to the company’s long-term survival than any single dental drug—their polymer-based, extended-release drug delivery system Atrigel.

“They quickly realized they had stumbled upon a very valuable platform technology for human systemic drug delivery,” says TOLMAR’s current CEO Mike Duncan. Around that time, the company began to build a more diverse product portfolio, acquiring a dermatology business and developing a prostate cancer therapeutic it recognized could be a blockbuster.

“We wanted to avoid a big-pharma buyout, because Eligard had such huge potential,” says Duncan. “We didn’t want to be acquired for one product and then have the rest of our business divested and sold off. We knew that we’d need to diversify in order to protect ourselves from being too attractive as an acquisition target.”

The strategy has paid off. Since that time, through a series of acquisitions and partnerships, TOLMAR’s current portfolio has grown to more than 25 marketed prescription products, with 25 additional product launches planned by the year 2020. Eligard is now the world’s second-leading treatment for prostate cancer. The company employs more than 450 employees in seven facilities around northern Colorado, and a large additional manufacturing plant is scheduled to open in 2016.

Colorado Springs-based Spectranetics has also found success in generating a diverse product line based on a focused platform. Spectranetics was founded 30 years ago to pursue the clinical development of excimer laser technology coming out of research at the Air Force Academy.

Today, the product lines of the company’s two principal business units address needs in peripheral artery disease, such as critical limb ischemia and in-stent restenosis, and in the lifetime management of cardiac implantable electronic device leads. But Donna Ford-Serbu, senior vice president of sales and marketing for Spectranetics’ lead management business, says the company always keeps the clinical need foremost.

“We focus on attacking specific clinical needs rather than developing any one specific tool,” says Ford-Serbu. “Going forward, we will continue our organic, research-driven growth while also supplementing our portfolio through business development as we find interesting innovations that fit with our clinical goals.”

In support of this product growth strategy, Spectranetics last year acquired AngioScore, Inc., a Fremont, California, based company that manufactures and sells cardiovascular specialty balloons. The company also recently completed the acquisition of the Stellarex™ drug-coated balloon angioplasty platform from Covidien.

Silvergate Pharmaceuticals, founded in 2010 and based in Greenwood Village, has married diversity with focus by identifying opportunities within a niche market that has
generally been overlooked by larger companies. As a trained pharmacist with 30 years of diverse pharmaceutical industry experience, President and CEO Frank Segrave had noted a recurring unmet need for reformulating approved pharmaceuticals for pediatric populations.

“By and large, big pharma companies have to concentrate their efforts developing molecules for mass markets,” says Segrave. “In hypertension, for example, they’re treating 30 million US adults with a drug like enalapril. The pediatric market is only about 100,000 kids, and that’s just too small to be viable for them.”

As a result, he says, while pharmaceutical companies evaluate drugs’ efficacy and safety in children, the commercialized drugs are often formulated as tablets and in adult-sized doses.

“Every day in children’s hospitals and in community pharmacies across the country, there are kids who need a specific approved medication but are too young to just swallow a pill,” says Segrave. “There is a strong need for drug formulations that meet the specific physiologic and developmental needs of children.”

The company’s first product, Epaned® (enalapril maleate powder for oral solution), was approved in September 2013, and several more are in the development pipeline. Segrave says that Silvergate Pharmaceuticals’ focus will remain on the underserved pediatric market, but within a very diverse range of disease states.

“Surefire Medical, based in Westminster, is another company whose platform technology holds the promise of diverse clinical application. The company was formed in 2009 by current CEO Jim Chomas, PhD, and co-founder Aravind Arepally, MD, who together developed the company’s Surefire Infusion System MT/LT. This catheter-based system delivers therapeutic agents directly to a desired treatment site within the peripheral vascular system—for example, the blood supply feeding a secondary breast-cancer metastasis within the liver—while the catheter’s expandable tip blocks reverse blood flow to improve therapeutic targeting. Again, although the company maintains a focus on its drug-delivery platform technology, the potential applications are broad and include delivery of drugs, radiation therapy, embolics and imaging agents for a wide range of disease states, including cancer, obesity and many others.

Founded in 2000, Boulder-based SomaLogic is yet another company developing a diverse product portfolio within a focused platform. The company’s commercial products are based on two interrelated technologies: a novel, proprietary class of protein-binding molecules called slow off-rate modified aptamers, or SOMAmers, and a multiplex proteomic assay called SOMAscan. Together, these innovations enable the simultaneous detection and quantification of more than a thousand distinct proteins in biological samples of interest. Several of the individual SOMAmers are now being evaluated for potential as therapeutic agents.

Byron Hewett joined SomaLogic as its CEO in 2013. Taking over for founding CEO, current chairman and Colorado bioscience icon Larry Gold, PhD, Hewett was charged with building out the commercial infrastructure of the company. He says that in principle each SOMAmer has commercial potential on its own and in combination with the others.

“Surefire Medical’s first product, Epaned®, an enalapril maleate powder for oral solution, is targeted to pediatric patients.

There is a strong need for drug formulations that meet the specific physiologic and developmental needs of children. – F R A N K S E G R A V E, P R E S I D E N T & C E O, S I L V E R G A T E P H A R M A C E U T I C A L S

Funding strategies influence corporate destiny

Although product diversity may prove to be an essential factor in a company’s commercial success, it is not enough to ensure independence. As Hewett explains, the pressures inherent to corporate financing and investment strategies can ultimately determine a company’s destiny.

“We’ve seen that one reason bioscience companies start up in Colorado but can’t stay here long-term is that there is a...
fundamental mismatch between many venture capitalists’ funding models and the healthcare product development life cycle,” says Hewett. “With a five-year life on their funds, VCs need an exit to recoup their investment and fulfill their obligations to their limited partners. But companies in this space need four to 10 years to get a product to market. That can be problematic for healthcare companies who rely on VC funding.”

Chomas agrees. “As a startup, you have to raise financing, of course—since 2009 Surefire has raised $26 million—but it has been a very tough environment. The product development cycle is slow for medical devices and other bioscience, and that can sometimes surprise investors who are used to the rapid innovation in software and technology fields.”

Hewett says that when Gold founded SomaLogic, his previous company NeXstar Pharmaceuticals had recently merged with Gilead Sciences. Gold was fortunate to be able to draw on this personal experience and the associated financial success to maintain close control over his vision for SomaLogic.

“Larry wasn’t very happy when they took the [NeXstar] science out to the West Coast,” says Hewett. “But when he founded SomaLogic, he was in a better position to fund the company himself. Of course he brought in strategic partners, but he specifically structured it so that he could maintain control and independence, and pursue his vision without undue pressure to cut an exit deal other than what was in the best interests of the company and shareholders.”

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This move turned out to be critical to the longevity of the company because, although the fundamental science behind the SOMAmer technology was sound, it was also so novel that the company had to spend nearly a decade of R&D fine-tuning the technical aspects of the product.

SomaLogic’s founder-financed strategy is somewhat unusual, and indeed the other companies profiled here have grown mostly through internally generated capital or public markets, or cite unusually patient venture investors. Hewett is optimistic, however, that Gold’s serial entrepreneurship model will become more common as the local cluster matures.

“When entrepreneurs succeed, they want to see others do the same,” says Hewett. “As more entrepreneurs gain experience and have good exits, we may see more reinvestment into the local economy as they support and nurture the next generation of startups here in Colorado.”

Close community fosters success
While the long-term outlook for bioscience startups in Colorado continues to improve, the question remains: what drives entrepreneurs to put down roots here, when running a bioscience company would arguably be so much easier on the West Coast or Eastern Seaboard? Intangibles like quality of life may always be a strong factor, but executives also cite a business culture that has more than made up for challenges they have faced.

“Of course we at Surefire Medical all love living in Colorado, but the closeness of the business community here has had significant benefits as well,” says Chomas. “I spent 15 years in the medical device industry in Silicon Valley, and there are just so many people there that you don’t feel like part of a tight-knit community the way you do here. Here we meet regularly with the universities, with the Colorado BioScience Association, and with state and local leaders to talk about our needs and help them understand how we can all work together to get things done. I would never have thought to go to the state of California for those kinds of discussions, but here it’s possible, and that kind of networking is powerful.”

In fact, the strength of those relationships proved enough for Surefire Medical to move their manufacturing facilities to Colorado from Miami Lakes, Florida. “While we were headquartered here from the beginning, we had a partner in Miami Lakes with a clean room, machine shop, ISO certification and a fully developed QC system to help us get our first product to market. And that area has a large concentration of companies in medical device manufacturing.

An illustration of a SOMAmer, or a slow off-rate modified aptamer, which is a novel proprietary class of protein-binding molecules developed by SomaLogic.
so it was helpful to be able to tap into that experience pool initially.” Eventually, however, the State, county and city provided Surefire with enough incentives and support that it made sense to bring the manufacturing facilities and jobs here to Colorado.

Duncan, too, sees underappreciated value in the closeness of the local bioscience community. He points out what he sees as reduced competition for the services of the FDA’s Denver District Office.

“Once it’s ready, our new plant won’t be able to come online until we have our FDA inspection,” he says. “With such a high density of companies in places like New Jersey, it can be hard to get time and attention from the FDA there. We’ve found the FDA here to be easy to work with—we can let them know what’s coming up with our construction so they can plan their workload, and just generally have a productive running dialogue with them.”

According to Segrave, community support was also fundamental to Silvergate’s success. “In just a few short years, we grew from a concept to an extremely small R&D enterprise to building an entire infrastructure including compliance, finance, legal, administration, sales, commercialization and more. We essentially built a company from nothing, and we had to figure out how to do everything from selecting a building to finding an IT provider. We found a great support structure here in Colorado, with people willing to say ‘whatever you need, we’ll help you figure it out.’”

Adds Hewett, “Larry came to Boulder 40 years ago as an assistant professor, and his commitment to Colorado is deep; this is home for him. But there’s a good business case for staying here, too. We have Nobel-prize winning scientists at the university, and they are the nucleus of a culture of invention and innovation. There is a lot of talent here, a lot of productivity here, and it makes sense to keep that in place and build up the commercial infrastructure around it.

“We can successfully attract high-quality employees from outside Colorado to fill in any gaps in knowledge and experience,” Hewett continues. “But at least for us, it is important they live as well as work here. The opportunities are so vast, we need them to be in it up to their eyeballs with the rest of us.”

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