

CHALLENGES ARE GREATEST FOR EARLY-STAGE LIFE SCIENCES COMPANIES



The cost of developing and bringing to market a novel therapeutic technology can reach a fully burdened expense of up to \$800 million, according to a life sciences strategic action plan developed by the state of California. Finding that kind of money can present big challenges for life sciences firms, especially for early-stage companies.

The current venture capital model is in some ways inconsistent with the capital requirements of life sciences startup companies, since traditional venture capital typically requires an exit strategy in the relatively near term. On average, clinical trials and FDA approval for a single therapeutic agent can take up to nine years. Even then, a startup company faces significant additional hurdles before it has a marketable product. For many venture capitalists, that timeline is simply too long.

A STRUGGLE FOR FUNDING

“The biggest challenge for early stage biotechnology companies is figuring out how to get funded,” says Steven A. Elms, managing director of New York-based [Aisling Capital](#) and former principal in the Life Sciences Investment Banking Group of Hambrecht & Quist. Besides the long time frames involved, life sciences investments also entail a high degree of risk: About 50% of Phase 1 drugs fail, he notes.

In “[Science Business: The Promise, The Reality and The Future of Biotech](#)” (Harvard Business School Press, 2006), author Gary P. Pisano, a professor of business administration at Harvard Business School, argues that there is a “fundamental and deep struggle between the conflicting objectives and requirements of the *science* of biotechnology and the *business* of biotechnology.”

DISCONNECT BETWEEN REVENUES AND PROFITABILITY

That conflict spans many areas, including differences in cultural norms, values and practices, Pisano notes, but at its core is the disconnect between revenues and profitability in the biotech sector over the past three decades. While revenues reached about \$36 billion by 2004, the overall sector remained in the red through most of that period and only began generating meager profitability halfway through 2003, according to Pisano’s research.

Not surprisingly, life sciences entrepreneurs recognize the scope of the challenge they face. In a 2006 survey of chief science officers at biotechnology companies conducted by the life sciences practice of Pepper Hamilton, a Philadelphia law firm, 100% of those polled cited securing financing as one of their top concerns.

“The biggest challenge for early stage biotechnology companies is figuring out how to get funded. Early-stage companies are usually focused on research and development and faced with the prospect of spending a lot of money before they ever get a product approved, which is why there are so few profitable firms in that segment.”

Nonetheless, many life sciences enterprises are successful in securing the financing they need each year, sometimes accomplishing that feat in novel ways. As Elms points out, it is important to acknowledge the distinction between profitability and return on investment for backers in any discussion of life sciences financing.

“Early-stage companies are usually focused on research and development and faced with the prospect of spending a lot of money before they ever get a product approved, which is why there are so few profitable firms in that segment,” he says. “However, there are other ways for investors to achieve ROI in this sector, including merger and acquisition activity and, for companies with Phase 3 clinical products with reasonable market expectations, public offerings.”

UNIQUE STRATEGIES TO SECURE FINANCING

Large pharmaceutical companies sometimes are willing to partner with early-stage biotech companies whose products they consider promising, and some big drug companies have launched venture capital arms to invest in startups. In addition, there are a number of life sciences specialist firms in the venture capital field, although most favor investments in mid-stage or later companies.

Because of the high failure rate for Phase 1 drugs, early-stage life sciences companies face the toughest hurdles. Companies with products in Phase 2 and Phase 3 clinical trials—where the results are likely to reveal if the drug will be efficacious—have more access to venture capital.

“For early-stage companies, focusing on securing government grants and working out of universities can be effective strategies,” Elms says. “Once you get into clinical development, you open up a whole new realm of investor. There is a lot of money available for mid-stage development, as long as the drug is unique. Investors will take efficacy bets if there is good clinical data pointing them in that direction.”

For more information, please contact Stash Lisowski at slisowski@gellerco.com.