

Strategies for success in today's competitive life sciences market

Insights for life sciences companies March 2011

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The life sciences industry is positioned for long-term growth, but navigating the business environment en route to commercialization is a continuing challenge for today's life sciences executives. The process of bringing a new product to market involves a series of complex and time-consuming activities — R&D, clinical trials, regulatory approvals, manufacturing, marketing and distribution — all of which require substantial funding.

Change is the only constant: What gets funded today might not get funded tomorrow or in the next stage, and regulatory and reporting requirements continue to evolve, as well. Despite these challenges, life sciences companies can apply the strategies for success discussed in this article to improve their ability to adapt and thrive.

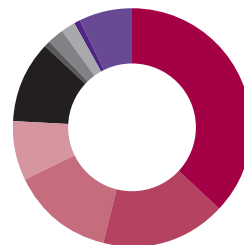
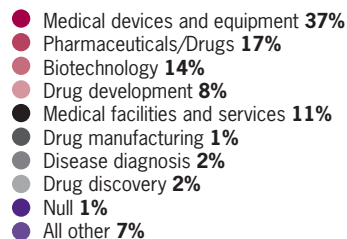
Industry challenges

Funding: In the capital-intensive life sciences market, funding has been hard to come by in recent years, with few IPOs and shrinking private equity and venture capital investment in 2009 and 2010. Although there are signs that this trend is starting to reverse, the yo-yo nature of funding patterns is an ongoing concern for life sciences executives seeking capital.

In the fourth quarter of 2010, 24 percent of venture capital deals —

totaling \$6.5 billion across all industries — were in the health care sector, which includes life sciences. Within life sciences, medical device and equipment companies, followed by pharmaceutical and drug companies, saw the most deals and received the most venture capital funding, according to CB Insights, a venture capital and angel investment information services company. Moreover, the average size of transactions was larger in life sciences than in other industries.

Venture capital deal volume in life sciences by sector, Q4 2010



Source: CB Insights, Q4 2010 Quarterly Venture Capital Report

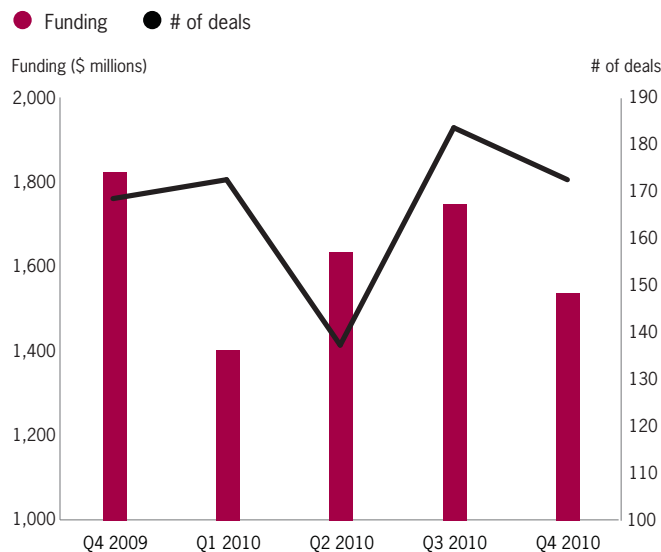
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Still, there are mixed signals. Although the health care sector saw a 2% increase in deals during 2010, year-over-year venture capital investment in the sector dropped 16%, as reported by CB Insights. Fourth-quarter results also showed a decline in total funding from Q2 and Q3, but early-stage activity in the health care sector hit a five-quarter high in Q4.

FDA approval: The time-consuming and often unsuccessful pursuit of FDA approvals is a source of significant frustration for life sciences companies. Regulatory milestones change frequently, and the agency's new 510(k) review process for devices that do not require full premarket approval (PMA) is also a concern for many companies. In fact, during a recent FDA three-city listening tour, life sciences companies expressed their frustration with the unpredictability of the approval process, which they say impedes funding for startups.

Changes to the 510(k) review process, which are the result of substantial input from the industry, will first focus on implementing specific actions to promote medical device innovation, increase regulatory predictability and assure patient safety. These steps will include streamlining the review process for innovative lower-risk products (the *de novo* process), improving training for Center for Devices and Radiological Health staff, and increasing the agency's reliance on external experts. Numerous additional items are on the agenda for evaluation, but no action will be taken without input from both the industry and consumers.

Venture capital investment and deal volume in life sciences (last five quarters)



Source: CB Insights, Q4 2010 Quarterly Venture Capital Report

Strategies for success

While some aspects of the funding and regulatory environment remain unsettled, continued global growth in the demand for health care looks all but inevitable. This growth, combined with the potential for breakthrough therapies and technologies, means that the long-term prospects for the life sciences sector appear robust. Moreover, by applying the following strategies for success, companies can enhance their ability to navigate the industry's complex and continually changing market conditions.

Target investors carefully. The challenge of finding investors intensified during the economic downturn and is still a significant hurdle for life sciences companies. Investors' tolerance for risk remains low but is likely to return quickly as conditions improve. At the same time, investors have become more focused on setting funding parameters. Although investment decisions in the life sciences sector have always been based on an evaluation of individual projects and products within a company's portfolio, investors were more willing in the past to invest in a company's overall portfolio. Now there is a growing preference for cherry-picking devices, research programs, and potential drug candidates.

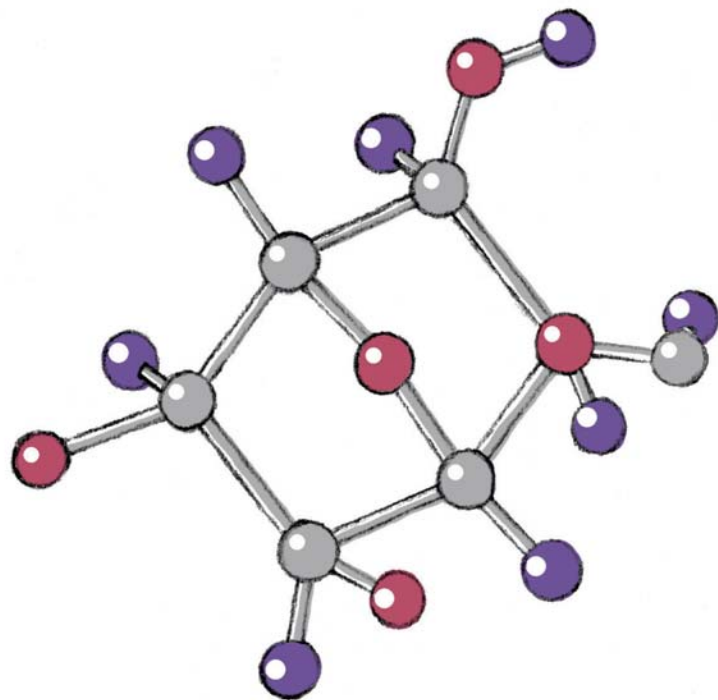
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To obtain funding in this environment, life sciences businesses need to be focused and creative in identifying funding sources and negotiating terms. Management should assume this responsibility, which requires proactive investor profiling and marketing of internal products and programs to ensure the right venture capital firms and large pharma companies have been targeted with investment opportunities. For example, if the goal is to raise financing for a drug or device in the diabetes market, management teams need to make sure they are talking to venture capital firms and large pharma companies that are interested in diabetes treatment and management. In addition, companies may need to be more open to deals that are specific to individual projects, programs and devices rather than their entire portfolio.

Adhere to strategic priorities. Given the high cost of drug and device development, life sciences companies cannot juggle a large number of projects. Executives must take a hard look at their business and determine which research projects, products and capabilities are central to their mission. Potential for revenue, attractiveness to investors and probability of success are, of course, primary considerations. Specific questions to consider include the following:

- What is the current or anticipated market potential for the product?
- Is the product in an area that is currently in vogue with industry players or financial investors?
- If the product is still in development, what is the estimated likelihood of success?

More and more, companies are closing, halting or jettisoning projects and products with the least attractive prospects, or those that do not correspond with a narrowed strategic focus. Companies must be proactive in identifying when it is time to put aside certain noncore research projects or products, or license them to a third party that is better positioned to exploit their potential.



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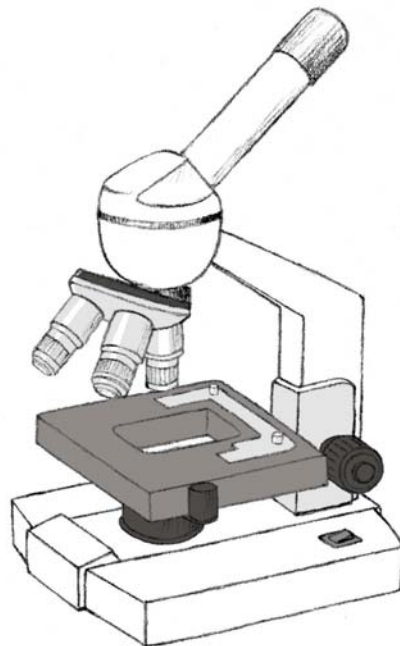
Explore new avenues for innovation.

Even in the midst of a difficult funding environment, there is room for innovation outside drug discovery. Wireless technologies related to patient care and health records are one area attracting interest from the venture capital community. Government grants and some not-for-profit foundations are also active in funding these projects. Expanding uses for new wireless technologies include patient adherence, medication delivery and management, remote patient monitoring, physician tools, and consumer health solutions. Of course, wireless transmission of health information does raise certain regulatory issues in that compliance with FCC, FDA and HIPAA regulations is required.

Pursue investors that have staying power.

Look for investors that are in it for the long haul. Early-round investors are increasingly angels and super angels. While these investors may meet immediate requirements for an early round of financing, they often do not have the wherewithal or commitment to continue funding and may not bring the needed resources to the company. Entrepreneurs need to evaluate these early-round investors in terms of not only the dollars they bring to the table, but also intangible attributes such as board leadership, quality of management advice, and industry and financing connections.

Later in a company's life cycle, an IPO is often discussed with great enthusiasm. In most industries, an IPO is a prime opportunity for investors to cash out; however, in life sciences, IPOs are often just another round of funding on the long road toward commercialization. And it will probably take several rounds of public offerings for a company to reach the end of that road.



Seek out expertise. The fast-changing, dynamic and highly competitive life sciences environment makes it exceedingly difficult for companies to be successful without having reliable guidance along the way. The landscape is continually shifting when it comes to tax, accounting, regulatory, investment and legal issues, any of which can have a major effect on your business. With this in mind, it is important to consult regularly with your investors, attorneys, accountants and other advisers. Not only will frequent consultation yield the most up-to-the-minute advice and information, but it also lets you stay focused on strategic priorities.

Keep the passion. It's essential for executives to retain their passion for their company's products and remember why they got involved in a life sciences venture in the first place. Passion is infectious; if you care about something, others are likely to care about it, too. Investors also sense passion and are more likely to commit to projects where people are emotionally invested. As one venture capital advertisement says, "We believe in believers."

A sense of optimism

While recent funding activity in the life sciences sector may at times resemble a roller coaster, there is reason to believe that capital will soon flow more freely. According to Grant Thornton LLP's 2010 Business Optimism Index, nearly half (47 percent) of business leaders surveyed believe that the U.S. economy will improve in the first half of 2011, and 79 percent feel optimistic about their own company's prospects in the coming months. This growing sense of optimism can only be a boon to funding and deal-making in the life sciences industry. •

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