Biotechnically Speaking

The business of life science breakthroughs has refocused and is on the rebound from the economic downturn

ometimes glitter isn't all that sparkles. Just ask prescription drug developers, who haven't had a real blockbuster since the 1990s. Sure, they're still working on potential home-run treatments that they hope will one day sell as well as Prozac or Viagra. These days, however, biotechnology firms are taking less high-flying, more sure-and-steady paths to increased profits.

Patience and discipline are paying off. Earlier this year, the Food and Drug Administration (FDA) opened the gate for Benlysta, the first new lupus drug to receive approval in 56 years. As a result, 19-year-old Human Genome Sciences now has its first drug on the market, and expects profitability by 2013.

This year has also opened doors to new therapeutic treatments for hepatitis C in the U.S. and for multiple sclerosis in Europe. Such promising developments are vindicating industry trends. This week's 2011 BIO International Convention in Washington, D.C. highlights effective strategies for maximizing returns on investment—not only in years ahead, but also right now. Topics include turning underutilized assets into dynamic revenue producers, and crafting lucrative licensing partnerships with pharmaceutical companies. Such brass tacks aren't especially sexy, but they're enabling the sector to remake itself for leanness and longevity.

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"Companies are struggling to recover from the economic crisis, and to accelerate growth, hiring and research," says Jim Greenwood, president and CEO of the Biotechnology Industry Organization (BIO), which represents 1,100 organizations with ties to the industry. "But we have seen very promising signs that the industry is in an upward swing."

Biotech refers to a diverse industry famous for turning life science breakthroughs into widely adopted products that dramatically change how people live. It includes not only research ventures that lead to new drug therapies, but also scientific innovations in

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food and fuel, from salt-tolerant crops and drought-resistant seeds to ethanol derived from algae and other plant matter.

Markets are responding as investors and joint venture partners maneuver to jump at today's emerging opportunities. The NASDAQ's Biotech Index (NBI) was up 15 percent through the end of May, outpacing most other sectors. There have been eight initial public offerings so far in 2011, coupled with increasingly large-scale mergers and acquisitions, according to BIO Industry Analysis.

Navigating tight capital markets over the past four years has been a tough but manageable challenge, as strategic concentration of resources has borne fruit. For years, companies have been scaling back their range of drug development programs, concentrating instead on core competency areas. Some who are strongest in neurology are no longer seeking cancer treatments, for instance.

In lieu of blockbusters, biotech firms are developing niche drugs for hard-totreat medical conditions, such as autoimmune diseases. Upon receiving regulatory approval, companies are now vigorously exploiting every possible commercial application. Result: Multiple revenue streams are helping firms to stockpile cash, attract investors and reinvest in programs to design the drugs of tomorrow.

For an example of biotech's resiliency, consider Human Genome Sciences (HGS). Launched in 1992, HGS initially ran the world's largest gene discovery laboratory; the company went public in 1993. But even as the world buzzed with excitement

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about mapping the human genome, HGS focused on practical applications.

"Since 2000, we've all been asking, "Where are the products?" says HGS president and CEO H. Thomas Watkins. "Where are the translations of those platforms and science breakthroughs into things that are going to improve people's health?"

HGS is now answering that question by running a tightly focused operation. Early on, company researchers built upon discoveries in proteins and antibodies, and by 2004, this biotech player had more than 10 drug development programs. Today, the HGS pipeline is leaner, with just five drug development programs that focus on its specialties, especially immunology and oncology.

Revenue streams at HGS haven't been waiting for Benlysta. Cash flow is generated by monetizing available manufacturing capacity for contract work, and from government purchasing of raxibamucab, an anti-anthrax drug not yet approved by the FDA. At the end of the first quarter, HGS held \$717 million in unrestricted cash and investments available for operations, according to its first-quarter report.

Today, HGS's top priority is to fully commercialize Benlysta around the globe; European Union approval is expected as soon as this summer. Research is divided between finding new applications for Benlysta, which might one day treat non-lupus conditions such as vasculitis, and moving other drugs through the pipeline.

To be sure, biotech still faces its share of challenges. Toughened regulations continue to pose hurdles as companies spend years, and sometimes up to \$1 billion, to get a drug approved. Amidst long horizons and long-shot prospects, backing from venture capitalists hasn't fully rebounded, hovering more than 25 percent below its 2007 peak. Only 9 percent of drug therapies survive clinical trials and go on to receive approval for market distribution, according to BIO Industry Analysis.

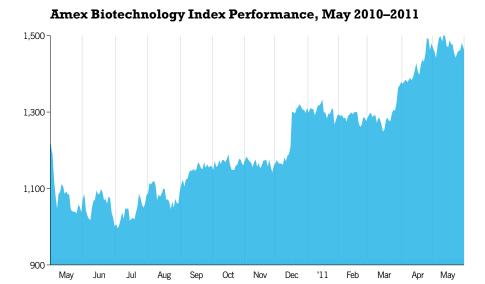
"The capital crisis has taken a real toll on this industry," Watkins says. "So there's a real question, from an industry standpoint, whether the innovation and success that we have had, and for now continue to have, will remain possible over the next generation, with access to capital such a huge challenge."

Risks and roadblocks notwithstanding, investors are acting on biotech's bright prospects. A late 2010 BIO Industry Analysis survey of more than 100 investment professionals found that more than half believe the industry is undervalued. Another 60 percent said they think it's a good time to invest in biotech. Through May, the Amex Biotechnology Index was up 40 percent over the prior 12 months, putting it far ahead of Standard & Poor's 500 Index (up 23 percent over the same period).

"Challenges with regulatory hurdles and small companies securing private financing remain," Greenwood says. Even so, he adds, "we remain cautiously optimistic."

Looking ahead, biotech leaders hope policymakers will help make the long road to market into a less onerous, less costly haul. They're making the case that biotech isn't a one- or two-region industry, but an employer of 1.3 million, with potential to benefit economies from coast to coast as today's strategies give rise to tomorrow's jobs. Lessons learned from lean, commercially focused drug developers could help guide the rest of the industry in years ahead.

"Biotechnology is paving the way for an industrial revolution that moves our economy away from a petrochemical-based economy to a greener, more cleantech-focused, bioprocessing-based economy," Greenwood says. "This could lead to a new homegrown value chain, giving every state the opportunity to sustainably leverage its local biological resources."



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