Biotech: A Big Future Behind It?

Despite a bumpy 2004, the rush to market hasn’t abated. The key for this crop of newcomers: Holding investors’ attention?

Private biotech companies and their investors opened 2005 like kids on Christmas morning: They hoped the window for initial public offerings that largely shut toward the end of 2004 would reopen, providing some much-needed cash for scores of growing companies.

Before the first days of February, things were looking pretty good. ViaCell (VIAC) started conservatively, at $7 per share on Jan. 21, and it has traded up 43% since. ViaCell was a great start for the year — a rare biotech IPO with a solid bank account and $32 million in revenues, thanks to a business storing infants' umbilical-chord blood for future emergencies. With four more traditional biotech companies ready to set their prices this week, the industry was ready.

Things didn’t turn out so well, however. Icagen (ICGN) of Durham, N.C., Favorlle (FVRG) of San Diego, and Threshold Pharmaceuticals (THLD) of Redwood Shores, Calif., all went public, but their first days on Wall Street were a struggle.

PROFITS? NOT HERE. Favorlle, which is developing cancer drugs, started trading on Feb. 2 at $7 per share — half the hoped-for $14-per-share price. Icagen, which is working on drugs to fight epilepsy, sickle cell anemia, and other diseases, opened on Feb. 3 at $8.05 per share, down from the expected $10 to $12. Trading for Threshold shares began Feb. 4 at $7, down from the target price of $14 to $16 a share. A fourth startup, CardioVascular BioTherapies, delayed its planned offering.

So what happened? As is often the case with biotechs, not one of the four is profitable. Moreover, Icagen was the only one with revenue — and just $5 million in annual revenues at that, according to 2003 figures (the most recent filed).

That’s not to say these companies don’t have potential. Icagen has partnerships with several Big Pharma outfits, including Abbott Laboratories (ABT) and Bristol-Myers Squibb (BMY), and Threshold had received a fast-track designation by the Food & Drug Administration for one of its drugs. "I thought Threshold and Icagen had some of the finest technology I’ve seen, and to come out like that was disappointing," says Franklin Berger, an independent biotech research analyst, investor, and former head of biotech research for J.P. Morgan.
PICKY BUYERS. Imagine that, investors spooked by a lack of revenues. But if the trend continues, this could be another tough year for Wall Street-aspiring biotechs -- just like 2004. Of the 36 biotech IPOs done from October, 2003, through the end of 2004, 24 had to cut their prices to find buyers. Only 17 are still trading higher than their IPOs. Plus, only five have market capitalizations above $500 million. "Last year was a hard year to make money," says Thomas Dietz, co-CEO of investment banking firm Pacific Growth Equity.

Nonetheless, don't expect too many small outfits to be deterred. Fourteen have filed to go public -- and Dietz expects that number to double by the end of February. Why? There was an appetite for biotechs, and Dietz and others believe there still is, despite the disappointments. After all, 2004's IPO class was triple 2003's. And in 2002, no biotechs went public at all. "The buyers are out there and want to see the stories -- they're just selective," Dietz says.

For many biotechs, any IPO is a good IPO. Clinical trials are expensive, and venture-capital investors can't absorb all the costs. Unlike the high-tech industry, an IPO isn't time to cash in. Rather, it's another round of funding that may be necessary to keep afloat in this capital-intensive business. Once public, a follow-on offering is always possible.

LIVING WITH VOLATILITY. "The bottom line is VCs are happy to get these companies out at any price," says Tom Salemi, editor of the Venture Capital Analyst-Health Care Edition, a Dow Jones publication covering the industry. "The only thing worse than a bad IPO is any private financing."

There's a silver lining in this situation. If a few dozen outfits make it to the public markets this year, it could mark an important milestone for biotechnology. Traditionally, big bubble years occur where investors get carried away, followed by three years of nothing. Two years of tempered success could signal that the industry is maturing, and that public investors are getting more biotech-savvy. "This is clearly a sign of sophistication," Berger says. "In up markets and down markets, investors have learned to adjust to the volatility and inherent dangers of the industry."
Before the back-patting gets out of hand, however, keep in mind that aside from Google (GOOG) and a few others, tech IPOs haven't exactly come roaring back, either. That means investors looking for high-growth prospects have been more willing than usual to consider biotech, Dietz says.

If investors move back to their high-tech comfort zone, the execs of young biotech outfits could well end up looking back at the first week of February as having been their last chance to go public for some time to come.
II.
2.1 Please briefly describe the Tysabri crisis of Biogen. (10%)
2.2 What actions did Mullen take? (10%)
2.3 Please provide your comments on Mullen’s action. (20%)
2.4 What is your forecast of Biogen’s future, and why? (10%)

On the Hot Seat
At Biogen
How CEO Jim Mullen managed a drug crisis after alarming news broke

JAMES C. MULLEN, THE 46-YEAR-OLD CHIEF EXECUTIVE of Biogen Idec Inc., has a degree in chemical engineering—and the demeanor to match. He’s an unflustered, just-the-facts-ma’am kind of guy. So when he first learned that Tysabri, his company’s breakthrough drug for multiple sclerosis (MS), might be responsible for a deadly brain infection, he moved quickly but calmly to find out what happened and to make sure it didn’t happen again. And he did all this while sticking to a long-scheduled commitment to his four children: a family vacation in Florida.

Mullen received the first reports about the two sick patients on Feb. 18, in the company’s small conference room in Cambridge, Mass. He had no reason to expect such dire news. Just one day earlier, Biogen and Elan Corp., the co-developer of Tysabri, had released results from a two-year clinical trial showing that the drug was safe and highly effective. Tysabri had received an expedited approval by the Food & Drug Administration last November, and analysts were predicting that the drug would hit $2 billion in annual sales in short order.

RARE BRAIN DISEASE
THE TURN IN FORTUNES was extreme and rapid. Dr. Burt A. Adelman, Biogen’s executive vice-president for research and development, told Mullen within an hour of learning the news that at least one and possibly two patients in the ongoing clinical trial of Tysabri had developed an extremely rare brain disease—progressive multifocal leukoencephalopathy (PML). “The mere fact that this bounced immediately to my office showed how serious the situation was,” says Mullen. He quickly issued orders: Alert the FDA at once, marshal all known facts, and inform every doctor involved in the trial. With a methodical investigation in place and responsibilities delegated, Mullen took off for Florida.

None of Biogen’s executives was surprised that Mullen left the premises given his dedication to his family. But colleagues also noted that it wasn’t much of a vacation, since he was constantly in touch by phone. “He was very calm, as always,” says Craig E. Schneier, executive vice-president for human resources. “He instituted the appropriate procedures. We never felt any sense of panic.” Still, Schneier acknowledged that “I instantly felt better once the boss was back,” on Feb. 25. By then, the first patient diagnosed with PML had died; three days later, Biogen, in consultation with the FDA, decided to suspend sales of Tysabri.

The drug’s removal left doctors, employees, and patients in shock. PML is extremely rare and, although Biogen had been monitoring trial patients for infections, Mullen says they never anticipated this disease. The disappointment within Biogen was enormous. “I’ve seen people weeping in the halls,” says Schneier. Even so, once the diagnosis was confirmed, Mullen felt there was only one responsible action. “Here was a risk that we didn’t understand, and patients had other options. Stopping the drug was the right thing to do.”

Some investors, however, criticized the company for pulling the drug too precipitously, and Biogen’s shares plunged 42.6%, to $38.65, the day the drug was withdrawn. A few days later a shareholder lawsuit was filed, charging that Biogen had withheld information about the risks associated with Tysabri. Mullen says he never considered the legal ramifications—“the first time I got aggravated was when I was talking to too many
had any profits to report. “Those setbacks were more threatening to the core of the business,” says Mullen.

He didn’t initially choose to work in such a risky industry. After graduating from Rensselaer Polytechnic Institute in 1980, he took a job at the former Smithkline. “I figured it would be a challenge,” he says. Nine years on, he decided it wasn’t so challenging and joined Biogen, then a tiny startup. Mullen distinguished himself by taking on an assignment far afield of engineering: In 1996 he moved to Paris to build Biogen’s European sales operation. “I didn’t know what I was doing,” he says. “That was a blast.”

Mullen returned to Cambridge to take over as CEO in 2000, and three years later merged Biogen with Idec Pharmaceuticals Inc., turning two struggling companies into the world’s No. 3 biotech. Besides Tysabri, Biogen sells four other drugs, including Avonex, the best-selling MS treatment.

Tysabri was meant to take Biogen to a new level of profitability. The drug marks a novel approach to treating MS by preventing rogue immune system cells from entering the brain and attacking the myelin sheaths that protect nerve fibers. In clinical trials, Tysabri proved twice as effective as older interferon-based drugs, and had far fewer side effects.

Those results prompted some 5,000 patients to take Tysabri in the four months it was available, and the company is getting 1,000 calls a day from MS sufferers eager to continue their treatment. But no one knows when, if, or in what form Tysabri will be available again. Biogen is meeting with medical experts and reviewing the records of all 3,000 patients in its clinical trials, a process that could take months. Analysts predict that the drug could return by 2006, but with very strong warnings that may scare off patients. Mullen refuses to make any such predictions. Like the engineer he is, he’s waiting for the facts.

—By Catherine Arnst in Cambridge, Mass.