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THOUGHT CONTAGIONS

Biotech Comes Down With Enronitis

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The biotech sector is sick. The industry that promises to cure cancer and AIDS can't cure itself.

And it's all so sudden. All last year I thought favorably of biotech as a "defensive growth" sector — a group of high-risk/high-reward technology companies that are working on the consumer staples of tomorrow, and are independent of the cyclical oscillations of the electronics-technology sector. And biotech was "defensive" in another sense: Last year some biotech companies suddenly found themselves the unexpected beneficiaries of the war on bioterrorism.

Last year the Amex Biotech Index lost only 8.5%, a remarkably strong relative performance for a risky growth sector in a year when the NASDAQ Composite lost 21.1% and the S&P 500 lost 13.0%. But in just the first three weeks of 2002 biotech has gotten clobbered — down 8.5% year-to-date, vs. a loss of only 3.5% for the NASDAQ and 2.5% for the S&P 500.

Judging by some of the most obvious symptoms, biotech is suffering from an acute case of **Enron**-itis. This disease is characterized by severe loss of share price caused by a sudden drop in investor confidence. Its onset is associated with delusions of grandeur, questionable self-dealing, political influence-shopping and omission of potentially material information. The only known cure is a course of class-action lawsuits followed by intense congressional investigation. Untreated, Enronitis can lead to bankruptcy.

For biotechnology, "patient zero" for today's bout of Enronitis is I**mClone Systems**. But a better name than ImClone might be ImPlode. With its stock down to $19.15 as of Tuesday's close, year-to-date it's down 58.8%. It's down 74.1% since its high last December. Why?

It all started on Dec. 28, when the **Food and Drug Administration** refused to file ImClone's application for its Erbitux antibody for refractory colorectal cancer. Investors were shocked because ImClone had hyped Erbitux heavily throughout 2000 and 2001 — the experimental drug had "blockbuster" written all over it. ImClone pointed to the approval of two other cancer drugs — **Novartis's** Gleevec and **Pharmacia's** Camptosar — and rode into the FDA review process with a highly unusual and daring "rush" application, made before all of the clinical data were in.

The buzz was so loud that **Bristol-Myers Squibb**, one of the global leaders in cancer medicine, paid a record $2 billion for a 19.9% stake in ImClone at $70 a share, acquiring at the same time the rights to comarket Erbitux in the world's most profitable pharmaceutical markets.

When the FDA rejected Erbitux, ImClone's management expressed surprise and assured investors that the drug was still on track for approval. Hey, rejections happen all the time at the FDA, right? You just have to tweak your trial results and reapply.

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But then an industry publication called the *Cancer Letter* somehow got a copy of the FDA's confidential response to ImClone, and it didn't match what management had told investors. The FDA noted material flaws with the design of the clinical-trial design, and what's worse, the FDA had told ImClone of these flaws way back in mid-2000. It's one thing that the company chose to ignore the FDA's advice, but more important, it failed to disclose that potentially material information to shareholders.

To add fuel to the fire, it now appears that ImClone's brash chief executive, **Sam Waksal**, and his equally brash operating chief and brother, **Harry**, had sold shares during the peak, even while they extolled the virtues of their drug to investors. And there have been reports that the company lent money to the Waksals to exercise options on ImClone shares ahead of the Bristol-Myers deal — and before the deal was publicly disclosed.

And if this weren't bad enough, it seems that ImClone's political influence may raise concerns as well — considering that its work is so highly regulated by the federal government. According to the biotech industry publication *BioCentury*, "Sam Waksal is linked to prominent **Democratic** politicians and media celebrities.... In 2000 Sam Waksal donated more than $52,000 to the party. According to **Federal Election Commission** records, he has given more than $140,000 to **Al Gore**, **Sen. Thomas Daschle** (D., Mont.) and other Democrats since 1996.... Waksal was a guest at the **Clinton** White House; he donated $20,000 and helped raise additional funds for **Hillary Rodham Clinton's** Senate campaign. In 2001, Hillary Clinton supported the campaign of Sam Waksal's daughter, **Elana Waksal Posner**, for New York City Council."

Now ImClone is mired in lawsuits, and the subject of a congressional investigation. Bristol-Myers probably wishes it had never heard of ImClone — but now perhaps the only way out for ImClone is to sell out entirely to Bristol. How low will the price for that deal have to be? But who else would want it?

The imPact of ImClone's imPlosion on the biotech sector is very real. Investing is always a "trust me" game, and all the more so when companies are betting on risky, experimental products subject to unpredictable regulatory scrutiny. Now ImClone has rubbed this reality right in the faces of biotech investors — and investors are demanding a new risk premium. Suddenly the whole industry is worth a lot less than it was just a few short weeks ago. Enron did it to the energy sector, and ImClone did it to the biotech sector.

My colleague at **Trend Macrolytics**, biotech analyst **Matthew Hougan**, says, "The situation is even worse in the case of ImClone because Erbitux was thought of as a sure thing. In evaluating any biotech product, investors have to read between the lines to figure out what chance that product has of making it through the FDA. Biotech companies don't open up the details of clinical trials for public evaluation, so your only choice is to rely on the signals from management and industry. And in this case, they were almost all flashing go. Hey, cancer-leader Bristol-Myers Squibb paid $2 billion for a piece of the action, and we all assumed they did their homework."

But now Hougan isn't so sure. "But did they do their homework? Now Bristol is refusing to disclose how much of the Erbitux data they saw. So can we trust them any more than we can trust ImClone at this point?"

But just as the broad troubles in the energy sector today can't be laid entirely at the feet of Enron, blame for the troubles in the biotech industry can't be laid entirely at the feet of ImClone, either. No, the sector's problems are more chronic and more systemic than just Enronitis.

Despite revolutionary leaps forward in science, earnings and profitability across the industry, the biotech sector has been slowly trading down for almost two years now.

One reason is that after a year in office, **President Bush** still hasn't appointed a leader for the Food and Drug Administration. Charged with making the life-and-death decision of whether to green-light a new drug — knowing that needy patients may suffer if the drug is turned down or delayed, but also knowing that many will suffer if the drug turns out to have terrible side effects — the FDA needs strong leadership to find the courage to do its job.

Another problem is that the FDA is woefully underfunded, with a budget that's growing far less rapidly than the pace of scientific innovation the agency is intended to regulate. The FDA itself admits that the average review times for new drugs lengthened to 14 months from 12 during 2000. Chances are good that the lag time rose again in 2001, too.

And the delays are even longer for the most innovative and most important drugs — the ones now pouring out of the biotech industry. With estimates putting the cost of developing a new drug as high as $800 million, the last thing we need to do is make it more difficult for these promising medicines to make it to market simply because a regulator doesn't have enough money to do its job in a timely manner.

Biotech remains the single greatest hope for improving the human condition on a global basis. And humanitarian considerations aside, that means that biotech companies are in a position to make a lot of money. Beautiful dreams indeed. So it's all more tragic when managerial misconduct and bureaucratic inefficiency get in the way of those dreams. TM