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Search for Profits

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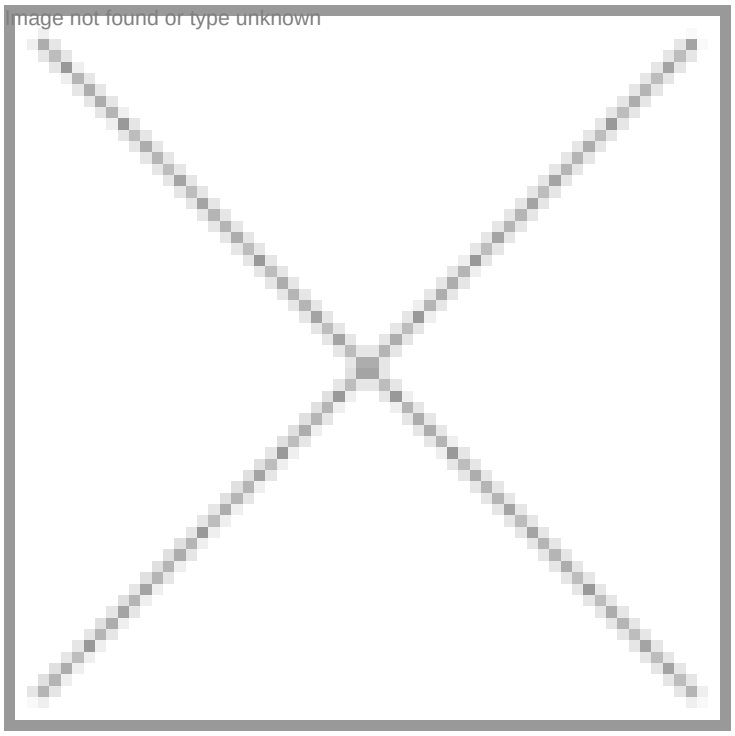

Search for Profits

As the global biotechnology industry enters 30 years of existence, there is a collective drive towards profits which has eluded most of the companies in this research-intensive sector.

There are nearly 1600 biotech companies in the US. In all, 340 of them are publicly traded companies and accounted for two-thirds of the US industry's biotech revenues of $43 billion. Of these, only a dozen companies have shown recurring profits.

According to an investment note written by Frank DiLorenzo, biotech analyst at Standard and Poor's, market capitalization was not the ideal way to judge the worth of a biotech company. His prescription: look for companies with strong product portfolios and a healthy research pipeline.

" Look for illnesses that aren't adequately treated," he was quoted in Philadelphia Inquired newspaper during BIO 2005 in June. New products that duplicate existing therapies "are unlikely to achieve commercial success," he noted.

Blockbuster biotech drugs

Product	Company	Treatment Details	Global sales in 2004 In US $ billion
Procrit	Johnson & Johnson	Anemia	3.99

Sources: IMS Health & Philadelphia Inquirer

The companies to watch out for in the US are: Genentech, San Francisco, Amylin Pharmaceuticals, San Diego and Renovis.

Genentech has a slew of notable drugs in its portfolio such as Avastin, Rituxan and Herceptin, all antibodies for cancer treatment. Avastin was initially approved for colorectal cancer and has also showed promise in treating breast and lung cancers. Phase 3 clinical trials for these treatments are currently on.

Amylin is allied with Eli Lilly and has recently received regulatory approvals for Byetta, a drug that stimulates insulin production in diabetics, and Symlin, a drug that curbs blood sugar after meals. Of course, there are some concerns about this drug causing nausea as a side effect.

Renovis has a drug to treat strokes, Cerovive. In May, Renovis has signed a $170-million partnership deal with Eli Lilly.

The performance three large mutual funds focused on biotech industry provides some clues. Fidelity Select Biotech Fun has $1.5 billion in assets. iShares NASD Biotech Fund with $1 billion and the $500 million-Franklin Biotech Discovery Fund are the prominent biotech funds.

Till May end, the Fidelity Select Biotech was down six percent. The fund was up 12 percent last year and 33 percent up in 2003. In 2002, the Fidelity fund was down 41 percent and it lost 25 percent in 2001.

According to the 2005 Ernst & Young Global Biotech Report, the industry collective lost $17 billion in the last three years. As a group, biotech industry is likely to achieve profitability by 2009 or 2010 only. The report said companies could only increase operating profits through some combination of revenue growth and cost containment.

"However, as the biotech sector moves towards increased profitability, it faces potential challenges on both the revenue and the cost side of the equation," wrote E &Y's Michael S Hildreth in the report.

Hildreth said another potential constraint on the revenue side was the blockbuster model.

Drugs pulled from the market

Approval Date	Drug	Treatment Details	Associated Risks	Withdrawal Year
2004	Tysbari	Multiple sclerosis	Rare, frequently fatal demyleinating disease of central nervous system	
2001	Bextra	Pain reliever	Heart attack/stroke; fatal skin reactions	
1999	Vioxx	Pain reliever	Heart attack/stroke	
1997	Baycol	Cholesterol	Severe damage to muscle, sometimes fatal	
1999	Raplon	Anesthesia	An inability to breathe normally	
1993	Propulsid	Heartburn	Fatal heart rhythm abnormalities	
1997	Rezulin	Type 2 diabetes	Severe liver toxicity	
1988	Hismanal	Antihistamin	Fatal heart rhythm abnromalities	
1997	Raxar	Antibiotic	Fatal heart rhythm abnormalities	
1997	Posicor	High blood pressure	Dangerous interactions with other drugs	

1996	Redux	Obesity	Heart valve abnormalities

Source: Burrill & Company

The underlying science has already been moving in the direction of targeted medicine.

NitroMed's BilDil, currently awaiting FDA approval, could become the first drug targeted to a specific demographic group, he noted. "While this could be revolutionary in transforming medicines from blunt instruments of yesterday to the finely honed scalpels of tomorrow, it would also almost certainly lower the market size for these drugs," writes Hildreth.

Problems in innovation

According to G Steven Burrill of Burrill and Company, the innovation pipeline is running into to regulatory obstacles. Estimates suggest that only one-third of the 415 new drugs approved between 1998 and 2002, were new molecular entities (NMEs). Only 14 percent were considered by the US regulator, FDA, to be a " significant improvement" over existing products.

The drugs development costs are high, according to Burrill, due to:

- Extremely high pre-IND (investigational new drug application) failure rate of NMEs
- Less than 1 in 5 INDs for NMEs make it to NDAs (new drug applications)
- Time from IND to market is 8-10 years
- Cost per NME is $800 mil lion
- Multiple review cycles for most NME NDAs
- For drugs completing phase2, the failure rate in phase 3 has increased to 50 percent as compared to 35 percent a few years ago.
- In 2003, Merck terminated phase 3 development of MK-0869 for depression and MK-767 for diabetes at a cost of $800 million and exposing thousands of patients to un approved drugs

However, the good news is that the biotech industry will continue to outpace the pharmaceutical sector, with the seven largest biotech companies growing at rates faster than the pharma industry's 9.1 percent average, according to Wood Mackenzie And Tufts Center for the Study of Drug Development estimates that of about 250 protein-based therapeutic products currently in development worldwide, 33 recombinant DNA protein and 16 monoclonal antibody therapeutics are likely to receive US regulatory approval.

Narayanan Suresh in Philadelphia