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http://www.nytimes.com/2004/10/07/business/worldbusiness/07chiron.html?oref=login&oref=login&8br=&pagewanted=print&position=

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A Biotech Company's Aggressive Move Backfires

By ANDREW POLLACK

oward Pien, the chief executive of Chiron, said he wanted to help meet America's need for more flu vaccine, while expanding the business of his company. So Mr. Pien has been sharply increasing the production of flu vaccine at a British factory Chiron acquired in 2003.

The company had expected that plant to supply about 50 million vaccine doses to the United States this year, up from 26 million in 2002, when the plant was owned by another vaccine maker.

But now Mr. Pien's aggressive plan has backfired. Finding contamination problems, British regulators suspended the license for vaccine production at the factory on Tuesday, a move that will deprive the United States of nearly half the flu vaccine it expected for this winter. The suspension has cost Chiron not only three-quarters of the profit it expected this year, but also some of its credibility with investors and customers.

Some analysts downgraded Chiron's stock, and Moody's Investor Services said it was looking at lowering the company's debt rating. Mark Augustine, an analyst at Credit Suisse First Boston, called Chiron a "broken" biotechnology stock. Shares of Chiron plummeted 16 percent on Tuesday, rebounding very modestly yesterday to close at $38.32, up 34 cents.

Vaccines accounted for about $700 million of the company's $1.75 billion in revenue last year. Fluvirin, the flu vaccine, alone accounted for $219 million. With the big increase in production, analysts had expected more than $300 million in revenue from Fluvirin this year.

Chiron, anticipating increased revenue, had increased spending in research and development and other areas of its business. It is also building a new office for its vaccine business in Philadelphia. Now the company may have to scale back plans. And prospects for its future flu vaccine business are clouded.

Mr. Pien has said that the company remains committed to being a major flu vaccine supplier next year. But he conceded in a news conference Tuesday that addressing the problems at the factory might extend past next February or March, when production would have to begin for next winter.

Mr. Pien, who rose quickly in the management ranks in several major pharmaceutical companies before becoming chief executive of Chiron in April 2003, did not make himself available for an interview yesterday. He said on Tuesday that the British regulatory decision was "disappointing and unexpected, but we respect the regulatory authority's judgment because it is based on concerns over safety."

One question is whether the contamination problems may have been a consequence of Mr. Pien's push to increase vaccine production quickly at the aging factory.

"The problem was they really stressed the system this year to get to that 50, 52 million doses," said Geoffrey C. Porges, an analyst at Sanford C. Bernstein & Company who formerly worked in the vaccines business at Merck.

David V. Smith, Chiron's chief financial officer, said yesterday that the company had not expanded its production too fast. About $75 million has been spent to upgrade the factory in the last five years, the company said. Chiron said it is committed to spending another $100 million to replace part of the plant.

The plant, located in Liverpool, dates back to the 1970's and has had a series of owners and problems in the last decade as pharmaceutical companies merged and divested assets.

Chiron acquired the owner of the Liverpool plant, PowderJect Pharmaceuticals, in July 2003 to expand its vaccine business. That merger was completed shortly after Mr. Pien took over, though the deal had been planned before he arrived. PowderJect, in turn, had acquired the factory in 2000 from Celltech, which owned it for about seven months.

Contamination problems were not new. Polio vaccines manufactured by Medeva, another previous owner, at the plant before 1996 were recalled in October 2000 after British authorities said they might be contaminated with BSE, or mad cow disease. In 1999, the Food and Drug Administration notified Medeva that there were risks of contamination in the flu vaccine produced at the plant.

Production issues at the plant when it was owned by Medeva also caused delays for Aviron, the developer of the nasal spray flu vaccine. The manufacturing of the spray vaccine, called FluMist, is still done partly on the same Liverpool campus but that production is now under the control of MedImmune, which acquired Aviron.

"It's an old facility that was sold by Glaxo to Medeva, who spent some money on it, though probably not in the right spot, then to Celltech, who didn't give a toss," said one British pharmaceutical executive.

Still, J. Leighton Read, the former chief executive of Aviron, said that he would not necessarily blame the age of the factory for Chiron's problems.

"Every vaccine plant that's more than a year old that I'm aware of has a history of challenges in complying with the regulatory regime," said Dr. Read, now a venture capitalist. "In our extreme concern for safety, which is largely appropriate, we have evolved systems that are too rigid and brittle to adapt to circumstances such as this."

Chiron, based in Emeryville, Calif., is one of the nation's oldest biotech companies, founded in 1981 by three scientists from the University of California campuses in San Francisco and Berkeley. Perhaps its biggest claim to fame is the discovery of the hepatitis C virus.

But Chiron has not had as much success in developing biotech drugs as some of its competitors like Amgen and Genentech. The company has grown in large part through acquisitions and now has three businesses - drugs, the testing of donated blood for viruses like H.I.V. and hepatitis C, and vaccines.

The shutdown of its vaccine production could damage Chiron's business beyond the immediate loss of revenue. Hospitals, clinics and distributors might be more wary of ordering from Chiron in the future.

The federal government could become more aggressive in acquiring flu vaccine from additional suppliers next year, or encourage other companies to enter the business, which would cut Chiron's market share in the future. Chiron is currently one of two major suppliers of flu vaccine in the United States this year, the other being Aventis.

It is also possible the government will become more cautious in expanding its recommendations on who should get flu shots. "I took down my flu vaccine forecast right through 2012 because of this," said Mr. Porges of Sanford C. Bernstein.

Investors might also become less trusting of Chiron management. Mr. Pien gave public assurances, including in Senate testimony last week, that although the company had detected a limited contamination problem in the Liverpool factory, it was close to correcting the problem and would be shipping flu shots early in October.

"It certainly raises eyebrows in the investment community," said Mr. Augustine of Credit Suisse.

Argeris N. Karabelas, known as Jerry, who was Mr. Pien's boss at SmithKline Beecham in the 1990's, defended his credibility. "I can tell you there is nobody more credible that I've ever worked with than Howard Pien," said Dr. Karabelas, now a venture capitalist in Princeton, N.J. "This guy, if he said it, he believed it totally."

Mr. Pien, who was born in Taiwan and has an engineering degree from the Massachusetts Institute of Technology and an M.B.A. from Carnegie-Mellon, worked at Merck, Abbott Laboratories and SmithKline Beecham, which later became GlaxoSmithKline.

He became head of most of the SmithKline pharmaceutical business at the age of 40. His last position before joining Chiron was president of international pharmaceuticals at GlaxoSmithKline when the company, along with others, dropped a lawsuit aimed at keeping cheap copies of AIDS drugs out of South Africa.

Heather Timmons contributed reporting from London for this article.
