

# Hemispherx finalizing fatigue drug filing

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STAFF WRITER

Hemispherx BioPharma Inc. is finalizing its new drug application for Ampligen, an experimental treatment for chronic fatigue syndrome that has spent more than 30 years in clinical studies.

Dr. William Carter, the Center City biotechnology company's chairman and CEO, said he expects the application will be completed in early April.

Carter said he is "cautiously optimistic" the company will be able to secure an accelerated review from the Food and Drug Administration, given the absence of any approved treatments for chronic fatigue syndrome.



Carter

The Centers for Disease Control and Prevention estimates the disorder afflicts 1 million people in the United States.

Accelerated reviews are typically conducted in six months, as opposed to the one-year review for most new drug applications.

If the company gets such status for its Ampligen filing, and the FDA approves the application without raising any issues, Hemispherx would be in a position to launch the product by the end of this year or early 2008, Carter said.

Carter expressed a sense of vindication that his company has reached this point.

"It's been a long and arduous journey. ... There were a lot of skeptics," he said.

The skepticism remains evident in the company's stock price. Hemispherx's stock was trading recently at \$1.69 a share, near its 52-week low of \$1.65.

According to documents filed earlier this month with the Securities and Exchange Commission, Hemispherx has

## UP CLOSE

**COMPANY:** Hemispherx BioPharma Inc.  
**LOCATION:** Philadelphia  
**CHAIRMAN AND CEO:** Dr. William Carter  
**TYPE OF COMPANY:** Biopharmaceutical  
**2006 NET LOSS:** \$19.4 million  
**2006 REVENUE:** \$933,000  
**52-WEEK HIGH/LOW:** \$3.85, \$1.65  
**RECENT PRICE:** \$1.69  
**MARKET CAPITALIZATION:** \$122.6 million  
**EMPLOYEES:** 52 full time, 19 part time  
**BIG DEVELOPMENT:** Finalizing new drug application for Ampligen, an experimental treatment for chronic fatigue syndrome.

Source: SEC, company, Yahoo! Finance

recorded an accumulated deficit of about \$167 million since its inception.

Hemispherx posted a net loss of \$19.4 million last year, up from a deficit of \$12.4 million in 2005. The increase was due primarily to higher research and development costs associated with Ampligen and Alferon N, which the company acquired in 2003, is a treatment for genital warts and Hemispherx's only FDA-approved product in the market. The company is testing both Ampligen and Alferon N as potential treatments for viral infections such as avian flu.

Carter co-invented Ampligen in the early 1970s when he was a researcher at Johns Hopkins University. Ampligen is a synthetic, specifically configured double-stranded RNA compound designed to work by stimulating and enhancing the ability of a patient's immune system to fight disease.

Initially, the drug was tested as a potential treatment for cancer and later for

AIDS then for chronic fatigue syndrome. Carter even tinkered with the idea of using the compound to treat tobacco and create a "healthy" cigarette.

Hemispherx has spent the past 15 years testing the drug as a treatment for patients with chronic fatigue syndrome. The company estimates the global market for an effective treatment for the disorder to be in excess of \$1 billion.

"We're not the first company to go into this disease category," Carter said.

In a presentation with stock analysts last month, the company noted drugs developed by a half-dozen major pharmaceutical and biotechnology companies — including GlaxoSmithKline, Shire and Cephalon — have been considered as potential treatments for chronic fatigue syndrome, but said none proved to be effective.

Jenifer Antonacci, a Cephalon spokeswoman, said the company's flagship drug Provigil, approved as a treatment for narcolepsy and other sleep-related disorders, was tested in patients with chronic fatigue syndrome about two years ago. She said the study was conducted by researchers from outside of the company, with Cephalon support. The clinical trial, which involved 14 patients, did not produce sufficient results for Frazer-based Cephalon to consider seeking approval to expand Provigil's label to include the disorder.

Matt Cabrey, a Shire spokesman, said that while company executives have discussed the potential of testing its products for chronic fatigue syndrome, Shire never launched any formal product development program and has no current plans to do so. Based in England, Shire's U.S. headquarters are in Wayne.

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# Ailing pension fund earns strong return

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Philadelphia poured \$400 million into its public pension fund last year, which was still severely underfunded by 47 percent.

Higher contributions by the city and its employees would be one way to fill the gap.

However, while the fund has its problems, it's also being recognized for improvements resulting in higher market returns — 14.8 percent gross last year, compared to 8.0 percent gross the year prior.

Money Management Letter called the Philadelphia Public Employees Retirement System "an early mover, continually seeking out opportunities for diversification" in crowning it medium-sized public plan of the year. Public pensions nationwide with assets between \$1 billion and \$10 billion were eligible for MML's sixth-annual Public Pension Awards for Excellence.

Both small and large changes were

made to improve the city's \$4.3 billion fund over years past, fund consultant Tina Byles Williams said.

"The city has some challenges that have been produced over the last 20 or so years, mainly the underfunding of the plan," Byles Williams said.

With continued minimum funding and a market return of 8.75 percent, it will take until 2035 for the fund to become fully funded, said Christopher McDonough, chief investment officer for the fund.

Moving the fund from the current 53 percent minimum to 70 percent funding would raise costs \$90 million over fiscal year 2008, according to the city's five-year plan offered by Mayor John F. Street. Such an increase would affect the city's ability to provide funding for other services while continuing tax cuts, the plan said.

"When you are underfunded you have to sort of be a little more creative in trying to close the gap," Byles Williams said of the changes to the fund since 2004.

Among the larger changes were an increase in allocation to private equity and

decrease in allocation to publicly traded equity. Allocation to U.S. bonds were also decreased and allocation was established in real estate and hedge funds. Global Treasury Inflation-Protected Securities (TIPS), portable alpha and convertible bonds were also introduced into the portfolio to increase returns.

The plan's 14.8 percent return last year included 10.9 percent on portable alpha, 7.3 percent on global TIPS and 12 percent on convertible bonds, MML noted.

"One of the key things for a pension fund is to be diverse across different asset classes," McDonough said of the changes. "You don't want all of your investments moving in the same direction, at the same time; if there is a downturn the entire portfolio will take a hit."

The plan was also scoured for passive portfolios — in which the only objective of the manager is to match an index for that particular area — and perennial underperformers, Byles Williams said.

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