Growth

Financial Health
Memphis company GTx on the verge of changing Tennessee’s biopharm landscape.
By Preston Lauterbach

What do you get when you cross the chairman of the University of Tennessee Health Science Center Urology Department with a commercial banker? The answer is GTx, a Memphis biopharmaceutical company poised to expand both its product line and impact on Tennessee’s biopharm industry.

Mitch Steiner (the urologist, now GTx CEO) and Marc Hanover (the banker, now COO) founded the company in 1997. “We’re a young company with two [Food and Drug Administration clinical] trials,” says Steiner. “If either one is successful, it will transform our company.”

Today, GTx has approximately 100 employees stationed on the UT Health Science Center (UTHSC) campus, as the company develops new drugs for prostate cancer treatment and prevention and a treatment for the loss of muscle mass and bone density associated with cancer, chronic kidney disease, and aging. GTx is the first publicly offered biotech company in Tennessee.

The GTx drug ACAPEODENE is being tested in two doses for different uses in men fighting prostate cancer or its onset. The 80mg dose is in phase III of its food and Drug Administration (FDA) clinical trial to determine its effectiveness in combating the side effects of prostate cancer treatment. The patient ceases to produce either testosterone or estrogen and experiences the male parallel to menopause, the constellation of health symptoms that occur in women who cease to produce estrogen. Osteoporosis, heightened risk of cardiovascular disease, and hot flashes accompany the male version just as they affect females.

The 80mg ACAPEODENE is designed to treat the loss of bone density, improve patients’ cholesterol profiles, and stop hot flashes and gynecomastia. The trial will finish at the end of this year, and GTx plans to report the data in the first quarter of 2008.

ACAPEODENE, in a 20mg dose, is being tested for the prevention of prostate cancer in high-risk patients. Men diagnosed with high-grade PIN — a pre-cancerous prostate lesion — have a 30 to 50 percent chance of developing prostate cancer within three years and an 80 percent chance of developing prostate cancer within six years. A 2004 clinical trial offered promising results, with a 48 percent reduction in cancer developed among patients on ACAPEODENE versus the placebo.

Ostarine, another GTx drug in testing, marks the company’s transformation from a specialty in men’s health to what Steiner describes as “using small molecules to treat hormone pathways.”

The promise of Ostarine lies in its potential to reverse the effects of muscle wasting in cancer, kidney disease, and aging. If all goes well, GTx will file for FDA marketing approval in 2010 and 2011 for Ostarine in its various uses.

Steiner anticipates immediate expansion should the GTx products pass any of the trials. “If you look at comparables, our company can easily end up being a player from the standpoint of being a billion-dollar-plus company. An approval would be our trigger to build our campus, which will effect the landscape of the city.”

MARKET GAINS
Stack shares of GTx have gone from $8.65/share on August 18, 2006 to $18.65/share on August 20, 2007

GTx licenses ACAPEODENE European rights to Ipsen LTD

ACAPEODENE clinical data featured at scientific meeting in USA Today

OSTARINE builds lean body (muscle) mass and improves functional performance in Phase II proof of concept clinical trial

Initiates Phase IIb OSTARINE cancer cachexia clinical trial

Announces OSTARINE improved insulin resistance in Phase II proof of concept trial

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