

FemmePharma develops new drug

New topical cream intended to alleviate breast pain

By SARAH E. MORAN
Staff Writer

RADNOR — Not being able to give or receive a hug isn't exactly the warm and fuzzy image that Mother's Day usually conjures up.

But, for the 26 million American women who complain of occasional breast pain — and the 3.9 million females whose symptoms are severe enough to warrant medication — mastalgia is an unpleasant and achy reality.

One solution to this condition — often but not always caused by the vicissitudes of a woman's menstrual cycle, and rarely associated with breast cancer — is on the way.

(Another form of mastalgia, noncyclical pain, can occur at any age and usually results from nonbenign breast problems such as cysts, musculoskeletal issues, medications or diet.)

FemmePharma Global Healthcare Inc., based in Wayne, is working on a topical prescription cream to alleviate chronic breast pain.

Fifty-year-old FemmePharma founder and chief executive Gerianne Tringali DiPiano expects Phase II clinical trials for the drug, still called FP-1198, to begin this fall.

The trial will involve 60 pa-

tients before expanding to hundreds more in Phase III.

DiPiano expects the drug will be approved for widespread use by 2009 or 2010.

A Tredyffrin resident, she founded FemmePharma, bankrolling it with her own savings, in 1996 after working 16 years in the big pharma industry for the likes of Baxter Health Care/American Hospital Supply Corp., Bristol-Myers Squibb, Sterling-Winthrop and Wyeth.

Her privately held company relies mostly on reformulated compounds whose patents have expired. In their former states, these compounds produced results but came with sometimes serious side effects.

The women's pharmaceutical health care market is formidable indeed, with global sales of more than \$70 billion in 2000 and expected to grow 16 percent a year, to \$116 billion by 2010.

Other FemmePharma products in development are for urinary urge incontinence, dysfunctional uterine bleeding in women just entering menopause, and a drug for dysmenorrhea (serious menstrual cramping.)

Potentially, the markets for these drugs are huge: 13 million, 18 million and 42 million, respectively.

Twenty-six million American women complain of occasional breast pain.



Gerianne Tringali DiPiano, founder and chief executive of FemmePharma.

Staff photo by Kim Dietric

Drug

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All three are delivered "regionally," DiPiano explained — meaning intra-vaginally, where the body absorbs and uses the drugs without side effects to the whole system.

DiPiano started her company because, as she explained it, "The legacy of women's health care was that drug therapies dealt mostly with contraception and hormone replacement. At the time, it was hard for big pharma to justify expanding into markets that only affected women."

She believes that women sometimes suffer from "trained helplessness" — which, to her, means, "Why complain about a health issue if you can't do anything about it?"

She condemns neither the drug industry nor physicians for this lack, but knows that her company fills a void.

Currently, venture capital investment supports FemmePharma and its 40 employees.

Also sustaining FemmePharma is the \$32 million that KV Pharmaceuticals, of St. Louis, paid last year for its still-experimental endometriosis drug.

Endometriosis occurs when the tissue lining the inside of uterus grows outside the uterus, usually on the surfaces of organs in the pelvic and abdominal areas. These are

places the tissue is not supposed to grow. (Endometriosis is the leading cause of infertility in American women today.)

Little more than a year ago, FemmePharma took several organizational steps to position itself to go public, eventually — a shift DiPiano fervently hopes will occur in the next two to three years.

Another goal is for FemmePharma to acquire either an already-marketable women's health care drug, or its license, to help put its name out among gynecologists and obstetricians, the principal specialists that FemmePharma's sales force will approach with new products.

FemmePharma's offices, off a bustling Route 30 in Wayne, are decorated in soft purples and lavenders. An avid athlete who likes to run, horseback ride and golf, DiPiano anchors papers on her desk with five-pound hand weights.

"Every once in a while," she told a recent visitor with a laugh, "I'll close my office door and do a few sets."

She comes by this naturally: Two of her three brothers are body-builders. (The oldest of five children, she also has a sister.)

DiPiano is married to Michael DiPiano, managing partner of NewSpring Capital Management, a venture capital company in King of Prussia. The couple has one daughter, 11-year-old Erin.

Asked what advice she'd give her fifth-grader on this Mother's Day, the diminutive DiPi-

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— GERIANNE TRINGALI
DIPIANO,
chief executive of
FemmePharma

ano contemplated her answer before responding.

"I'd tell Erin that I know about the struggle for equality," she said. "The fight for equal status is far from over. I'd tell her that who she is, inside and outside, will determine who and what she is. And I'll also tell her never to become an imitation man."

The DiPianos will spend Mother's Day with Gerianne's 75-year-old mother and ailing father at her parents' home outside Baltimore.

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