From the Philadelphia Business Journal :http://www.bizjournals.com/philadelphia/print-edition/2013/01/11/fda-is-readying-to-rule-on-nupathes.html

FDA is readying to rule on NuPathe's revised application for its patch to treat migraines

SUBSCRIBER CONTENT: Jan 11, 2013, 6:00am EST

John George
Senior Reporter- *Philadelphia Business Journal*
Email | Twitter | Google+

CONSHOHOCKEN — **NuPathe Inc.'s** experimental migraine headache treatment is getting a second crack at securing Food and Drug Administration marketing approval, 18 months after the agency rejected its initial application.

Since that time, the Montgomery County specialty pharmaceutical company has replaced its CEO, who was also its co-founder, cut its workforce in half, changed the name of its lead product, raised $28 million and restructured a loan.

The FDA is scheduled to rule on NuPathe's revised application for Zecuity — formerly known as Zelrix — on or before Jan. 17.

Company officials declined commenting on the upcoming ruling and the changes at NuPathe citing Securities and Exchange Commission "quiet period" rules, which restricts information released by publicly traded companies.

Zecuity is a transdermal patch worn on the thigh or arm, which delivers controlled amounts of sumatriptan, the most widely prescribed migraine medication in the market. Sumatriptan was the key ingredient in Imitrex, a GlaxoSmithKline migraine headache treatment that came off patent in 2009.

The Zecuity patch uses NuPathe's proprietary transdermal delivery technology, called Smart Relief, which allows for the rapid, yet tightly controlled, delivery of medicine using a process called iontophoresis. Iontophoresis relies on a mild electrical current to transport medication through the skin. The delivery method is designed to overcome side effects, which include a feeling of tightness in the chest and neck, that some patients get when taking sumatriptan.

Last week, the company received an additional patent for Zecuity that company officials said would extend the product's patent protection, should it secure FDA approval, through June 2028.

The FDA turned down the company's initial new drug application in 2011. The agency said the company established the efficacy of its migraine patch, but it raised questions related to the chemistry, manufacturing and safety of the product.

NuPathe responded to the FDA concerns and resubmitted its application last summer. The company's revised application included packaging improvements and the results from additional studies, one of which confirmed a safety feature of the product that stops the release of the drug if the patch is incorrectly applied.

Zecuity would become the first transdermal patch product approved for migraine headache treatment.

Migraines are severe and debilitating headaches characterized by intense throbbing or pulsing and often accompanied by nausea, vomiting, and sensitivity to light and sound. Migraines afflict an estimated 36 million adults and children in the United States, and cost employers more than $13 billion each year in lost work days, according to the Migraine Research Foundation in New York. Decision Resources, a health-care research and consulting firm based in Massachusetts, recently predicted the market for migraine therapies will increase from $3.3 billion in 2011 to $5.8 billion in 2021 in the seven key markets: the United States, France, Germany, Italy, Spain, the United Kingdom and Japan.

Among those who suffer from migraines is Jane Hollingsworth, NuPathe's co-founder and former CEO.

Hollingsworth stepped down from her CEO post and seat on the company's board of directors a week after the application was resubmitted. At the time, the company said she would continue to work with the company as a consultant. Reached last week, Hollingsworth said she is continuing to do everything she can to support the company as it works to get Zecuity approved.

"It is a much-needed product and will serve many migraine sufferers well once it is on the market," she said.

Former Auxilium CEO Armando Anido was recruited to take over as CEO of NuPathe. Anido previously worked in the migraine treatment area while a manager at GlaxoSmithKline in the late 1990s.

While the FDA was reviewing the revised application, Anido took action in October to slow the company's cash burn rate. The company announced its cutting staff to 20 from 40 people, and delaying development of a second product, a drug for the long-term treatment of schizophrenia and bipolar disorder, until it identified a co-development partner for the program.

Later that same month, NuPathe completed a $28 million equity financing that involved the sale units, priced at $2 each, with each unit consisting of 1/1,000th of a share of a newly designated Series A preferred stock and a warrant to purchase one share of common stock. The financing, the company said in documents filed with the SEC, was enough to fund operation into the fourth quarter of this year. Also in November, NuPathe entered into an $8.5 million loan agreement with Hercules Technology Growth Capital.

When the company issued its third quarter financial results, Anido said, "We now have the financial resources to achieve our key objectives: to obtain approval for Zecuity, to secure commercial partners, and to conduct additional pre-launch activities for [Zecuity]."

John George covers health care, biotech/pharmaceuticals and sports business.