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BIOWORLD® TODAY

THURSDAY
JULY 19, 2007

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 18, NO. 139
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Neurochem Gets 2nd Approvable For Kiacta; Analysts Pessimistic

By Trista Morrison
Staff Writer

Almost a year after Neurochem Inc. received its first approvable letter for Kiacta (eprodisate) in the treatment of AA amyloidosis, history repeated itself.

The Laval, Quebec-based company said late Tuesday that its wholly owned subsidiary, Neurochem Ltd., received a second approvable letter for the drug. Just as before, Neurochem will attempt to address the FDA's concerns without conducting another clinical trial, but analysts remain skeptical about both Kiacta and Neurochem's Phase III Alzheimer's drug Alzhemed (tramiprosate).

This skepticism appears to be shared by investors, who have pushed the stock price down from about $26 last fall to a 52-week low of $5.01 on Tuesday. Shares of Neurochem (NASDAQ:NRMX) dipped 60 cents on Tuesday

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Preparing For AzaSite Launch, Inspire Gets $75M Investment

By Jennifer Boggs
Staff Writer

With recently approved ophthalmic drug AzaSite expected to hit the market in just a few weeks as a treatment for bacterial conjunctivitis, Inspire Pharmaceuticals Inc. bolstered its cash position with a $75 million investment from private equity firm Warburg Pincus LLC.

Inspire, of Durham, N.C., entered a securities purchase agreement to sell $75 million of exchangeable preferred stock based on a price of $5.35 per common share. The deal, expected to close this week, will ensure the "successful launch of AzaSite," expected in mid-August, and will help fund the company's four Phase III-stage programs, said Tom Staab, Inspire's chief financial officer.

News of the financing lifted the company's stock by 23.2 percent Wednesday. Shares of Inspire (NASDAQ:ISPH)

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Edison, Penwest Enter Deal On Orphan Neurological Disorders

By Jim Shrine
Staff Writer

Penwest Pharmaceuticals Co., as part of a relatively new strategy to target niche neurological diseases, gained rights from Edison Pharmaceuticals Inc. to technology being developed for treating mitochondrial disorders.

Penwest gained exclusive worldwide rights to Edison's EPI-A0001 in all fields of use, and plans to take the product into clinical development next year for treating mitochondrial respiratory chain diseases, said Jennifer Good, president and CEO of Penwest. The indications involve neurological disorders resulting from defects in cellular energy metabolism.

Most of the focus at Penwest, of Danbury, Conn., has been on applying its formulations and delivery technologies to new and existing drugs. One example is Opana ER,

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Financings Roundup

Clinical Data Boost Vilazodone Work With $66M Public Offering

By Jennifer Boggs
Staff Writer

Clinical Data Inc. is adding $66 million through a public offering to help fund ongoing Phase III development of Vilazodone in depression.

The Newton, Mass.-based firm is selling 3 million shares priced at $22 each, and said most of those will be purchased by Randal Kirk, the company's chairman and largest shareholder. Kirk agreed to buy, through one or more of his affiliates, 2.25 million shares – or $49.5 million worth of stock – which would give him about a 48 percent stake in Clinical Data.

The company also offered underwriters Bear, Stearns & Co. Inc. and Lazard Capital Markets a 30-day option to purchase an additional 450,000 shares. If that option is

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AHC Media LLC

Penwest

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an oxymorphone-based pain product formulated with Penwest's extended-release technology that Endo Pharmaceuticals Inc. launched last year.

Good told *BioWorld Today* the plan at Penwest is to continue its reformulation and delivery work while separately building a portfolio of new chemical entities targeting neurological conditions, a strategy the company embarked on about a year ago.

Edison, of San Jose, Calif., is entitled to an up-front payment and a $1 million loan from Penwest, which also will provide research funding over the next 18 months. Those payments could total $7.5 million, with the majority going toward sponsored research, Good said.

Penwest then would have an option to extend the reach an additional 18 months. As part of the deal, it also got exclusive rights to develop a second drug candidate from Edison during the sponsored-research term. Edison is entitled to certain undisclosed additional option payments, as well as milestone and royalty payments.

Guy Miller, chairman and CEO of Edison, told *BioWorld Today* there is a lot of interest now in the area of antioxidants and neurology, with the question being whether anyone is "going to crack the code on converting an antioxidant into a drug. We at Edison have a really keen understanding of how antioxidants work and how to convert them into drugs.

"We teamed with Penwest because they have a very clear set of skills in neurology and drug development," Miller said. "We believe the combination of Penwest's capital and their passioned research and development team, and Edison's skills in redox drugs, is a winning formula to crack the code that people have been chiseling at for the better part of 20 years."

Edison was founded in 2005 with an initial plan to develop the EPI-A0001 compound series for orphan respiratory chain diseases, such as Friedreich's ataxia, Leber's hereditary optic neuropathy, coenzyme Q(10) deficiency and MELAS syndrome, or mitochondrial encephalopathy, lactic acidosis and stroke-like symptoms.

All such diseases involve genetic changes in enzymes that affect mitochondrial function. EPI-A0001 is an analogue of CoQ(10) designed to have improved drug-like properties.

Edison described the respiratory chain, named because the last link of the chain involves oxygen consumption, as an energy currency exchange device. Its platform focuses on redox medicinal chemistry, an oxidation-reduction approach.

Miller said Edison was approached by five prospective partners, with Penwest being "by far the most competent in terms of having a cogent strategy" for bringing technologies in, moving drugs forward and building a commercialization infrastructure.

He said the deal was not done because Edison needed the money, as evidenced by its plan to announce a Series B financing round next week.

Instead, he said, the deal was done because working with Penwest was the best way to move the programs forward.

Edison has forged relationships, and received grant funding, from a number of nonprofit groups, including the Muscular Dystrophy Association, Friedreich's Ataxia Research Alliance and Seek A Miracle.

The technology also may have applicability beyond orphan respiratory chain diseases. Edison last year partnered with Los Angeles-based CHDI Inc., a nonprofit organization that supports efforts in Huntington's disease. They plan to develop analogues of CoQ(10) targeted to reach the brain and address the mitochondrial component of Huntington's disease.

Miller said in addition to other neurodegenerative diseases, Edison – along now with Penwest – plans to study the technology in metabolic syndromes, inflammatory diseases and ischemic conditions. ■

OTHER NEWS TO NOTE

• **Genomic Health Inc.**, of Redwood City, Calif., said the Blue Cross and Blue Shield Association Medical Advisory Panel has concluded that use of Genomic Health's Oncotype DX breast cancer assay to inform decision making about adjuvant chemotherapy meets the association's criteria for women with estrogen receptor-positive, node-negative, tamoxifen-treated breast cancer.

• **Invitrogen Corp.**, of Carlsbad, Calif., has signed an exclusive agreement with **Biocon Ltd.**, of Bangalore, India, to market pharmaceutical-grade insulin to the global cell culture market. Insulin is a widely used growth factor to delay apoptosis in mammalian cell culture which leads to increased productivity. Terms were not disclosed.

• **KeyGene NV**, of Wageningen, the Netherlands, has established a joint lab for plant molecular breeding with the Shanghai Institutes for Biological Sciences (SIBS). The lab will operate within the Institute for Plant Physiology and Ecology of SIBS, a branch of the Chinese Academy of Sciences in Shanghai.

• **Living Cell Technologies Ltd.**, of Melbourne, Australia, has established a Level 1 American Depositary Receipt Program (ADR) sponsored by the Bank of New York. The company's ADRs will trade under the ticker symbol LVCLY and was effective July 17, and each ADR will represent 10 ordinary LCT shares. The ADR program facilitates the purchase of LCT stock in the over-the-counter pink sheet market by U.S. investors, who already hold more than 10 percent of its shares.