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BioWorld® Today

WEDNESDAY
AUGUST 18, 2010

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 21, NO. 159
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Osteotech Stock Jumps 63%

Eyeing Regenerative Medicine, Medtronic Acquires Osteotech

By Trista Morrison
Staff Writer

Medical device maker Medtronic Inc. staked a deeper claim in the regenerative biologics field by moving to acquire Osteotech Inc. for $6.50 per share, or $123 million.

The all-cash deal represents a 65 percent premium to Osteotech's closing price on Monday. The Eatontown, N.J.-based company's stock (NASDAQ:OSTE) jumped 63.5 percent, or $2.50, to close at $6.44 on Tuesday.

Minneapolis-based Medtronic makes pacemakers, defibrillators, glucose monitoring systems and a variety of other medical devices that generated $15.8 billion in revenues during the 12 months ended April 30, 2010. The firm's spinal and bone therapy division – where Osteotech will fit – specializes in surgical implants, some of which are made of metal and some incorporate Medtronic's Infuse

See Osteotech, Page 3

Will Shire's Exit Be Chelsea's Gain in Hypotension Market?

By Donna Young
Washington Editor

WASHINGTON – Spotting an opportunity, investors drove shares of Chelsea Therapeutics International Ltd. up 10.6 percent Tuesday after Shire plc reported it was withdrawing ProAmatine (midodrine) from the U.S. market.

The drug is used to treat orthostatic hypotension, a sudden decrease in blood pressure attributed to cardiovascular, endocrine or neurological disorders.

But Chelsea's Phase III medicine Northera (droxidopa) stands to fill the void, although it is under investigation for neurogenic orthostatic hypotension (NOH) – a somewhat narrower indication.

NOH results from a deficient release of norepinephrine, the neurotransmitter used by autonomic nerves to send signals to the blood vessels and the heart, explained Chelsea Chief Medical Officer William Schwieterman.

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Another Alzheimer's Bust

Lilly's Semagacestat Out; Gamma Secretase Still In?

By Jennifer Boggs
Assistant Managing Editor

Eli Lilly and Co. is putting the brakes on a Phase III-stage Alzheimer's disease program after interim analyses showed cognitive function actually worsened in patients on semagacestat compared to placebo, but that failure is unlikely to discourage companies with earlier stage programs against the same target: gamma secretase.

After all, the spectacular miss by Myriad Genetics Inc.'s gamma secretase modulator Flurizan in 2008 did little to dissuade others in the field, as many attributed that Phase III disappointment to Flurizan's lack of sufficient brain penetration. (See *BioWorld Today*, July 1, 2008.)

The reason for semegacestat's failure is not yet clear. Data from an interim analysis showed no improvement in cognition and the ability of treated patients to complete

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NewCo News

Fabrus Forges Ahead with Therapeutic Antibody Platform

By Catherine Shaffer
***BioWorld Today* Contributing Writer**

Fabrus LLC, whose name means "Functional antibodies R Us," spent its first three years under Pfizer Inc.'s wing developing a therapeutic antibody discovery platform before it was spun out into independence just eight months ago. The biotech decided there was a need to find a new way to discover antibodies.

Fabrus, the first occupant of New York-based Pfizer's business incubator in La Jolla, Calif., spun out in January. "We decided there was a need to find a new way to discover antibodies because all of the antibodies on the market today are high-affinity antagonists," Fabrus founder and CEO Vaughn Smider told *BioWorld Today*.

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INSIDE:

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Clinic Roundup

• **BioMarin Pharmaceutical Inc.**, of Novato, Calif., said the first patient started treatment in its double-blind, placebo-controlled, randomized 28-week Phase IIIb PKU-016 study to evaluate the effects of Kuvan (sapropterin dihydrochloride) on neuropsychiatric symptoms in patients with phenylketonuria. The study plans to enroll about 200 patients 12 or older at about 40 sites in the U.S. and Canada. BioMarin expects to report results in the first half of 2012.

• **BiondVax Pharmaceuticals Ltd.**, of Ness Ziona, Israel, received approval from international regulators to start a Phase II trial of its universal influenza vaccine candidate, the Multimeric-001. The study is designed to include a total of 160 subjects randomized into three groups: a treatment group to receive the 500 mcg adjuvanted formulations of the Multimeric-001 vaccine, and two control groups that will receive adjuvanted and nonadjuvanted placebo formulations, respectively. Dosing is expected to begin in October, with data available by the end of the second quarter of 2011.

• **Palatin Technologies Inc.**, of Cranbury, N.J., reported positive Phase I data showing that subcutaneously administered bremelanotide, a melanocortin agonist candidate for erectile dysfunction and female sexual dysfunction, demonstrated consistent therapeutic blood plasma levels without sustained clinically significant blood pressure effects. Palatin intends to meet with the FDA to discuss trial designs for further testing, including a proposed Phase II trial of subcutaneous bremelanotide as a monotherapy and in combination with a PDE5 inhibitor such as Viagra (sildenafil, Pfizer Inc.) in men with erectile dysfunction who are not responsive or are inadequately responsive to PDE5 inhibitor therapies alone.

• **Xenon Pharmaceuticals Inc.**, of Vancouver, British Columbia, started a Phase II trial of topical XEN042, a compound targeting sodium channel subtype NaV1.7, in postherpetic neuralgia. The study is expected to conclude in the first quarter of 2011, with data available in the second quarter of 2011.

Coming Thursday in *BioWorld Perspectives*:

BioPharma: An 'Industry Ripe for Disruption'?

The quote "an industry ripe for disruption" comes from a recent special report in *The Economist* acknowledging the 10th anniversary of the announcement of the draft map of the human genome. Sadly, after an effort that cost in excess of $3 billion (not including the private effort), the hyperbole surrounding the initial announcement of the map now seems part of a different era – a golden age of optimism – pre-9/11, subprime meltdown, sovereign debt and vampire squids, where all seemed possible if only an expert could say it was so.... Tune into this week's *BioWorld Perspectives* in which Contributing Writer Mike Williams discusses the promise of the genome map.

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Stock Movers

08/17/10

Company	Stock Change	
Nasdaq Biotechnology	+$7.15	+0.85%
Alimera Sciences Inc.	+$0.89	+12.9%
Albany Molecular Research	+$0.46	+7.5%
Chelsea Therapeutics	+$0.34	+10.6%
Cardiome Pharma Corp.	-$0.41	-5.6%
MannKind Corp.	-$0.60	-8.8%
Osteotech Inc.	+$2.50	+63.5%

(Biotechs showing significant stock changes Tuesday)

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Osteotech

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Bone Graft. The division accounts for about 22 percent of Medtronic's annual revenue, and the company sees plenty of room for growth in the biologics space.

"We see substantial opportunities during the next five to 10 years to help more patients with biologics and regenerative therapies," said Tom McGuinness, general manager of Medtronic's Biologics business, in a statement.

Medtronic spokeswoman Marybeth Thorsgaard explained that the company is positioning itself at the intersection of medical devices and biologics, where a medical device can be used to deliver a biologic product. That's the strategy behind the FDA-approved combination of the LT-Cage Device and the Infuse Bone Graft for spinal fusion surgery, and Medtronic is under FDA review with another spinal surgery product that combines a metal fixation device with Medtronic's Amplify recombinant bone graft (rhBMP-2 Matrix).

Thorsgaard added that the company is working on device-biologic combinations for pain management, as well.

Osteotech markets a variety of bone graft, bone matrix and biocomposite products for use in musculoskeletal surgery. The company was profitable in 2006, 2007 and 2008, but swung to a loss in 2009 thanks to customer losses and the declining economy. In the second quarter of 2010, Osteotech returned to profitability, generating $24 million in revenues and posting $115,000 in net income, while ending the quarter with $10.7 million in its coffers.

Of course, Osteotech's financials are a drop in the bucket to a company of Medtronic's size. But what Osteotech brings to the table is complementary products offerings. While Medtronic is focused on spine, orthopedic trauma and dental products, Osteotech's portfolio will allow the company to expand into joint reconstruction, sports medicine and foot/ankle surgeries.

Additionally, Osteotech is under FDA review with the BioGenesis Dural Regeneration Matrix, the first product from its Human Collagen Technology platform. The engineered collagen product is designed to repair or replace the dura mater in various cranial surgical procedures.

For Osteotech, the Medtronic acquisition offer was likely welcome news. Last year, a low stock price prompted the company to hire Deutsche Bank Securities Inc. to explore strategic alternatives aimed at enhancing shareholder value. But the process wasn't moving fast enough for a group of dissident shareholders, who in January tried to take over the company.

The shareholders – including Heartland Advisors Inc., Boston Avenue Capital LLC and various entities affiliated with Spencer Capital Partners LLC – argued that Osteotech was underperforming its peers, draining its cash and failing to grow revenues. They also questioned the company's board composition and anti-takeover measures.

Osteotech and the dissident shareholders have fought back and forth in press releases and SEC filings, with the shareholders seeking to place four directors of their choosing on Osteotech's board at the firm's upcoming annual meeting. Presumably the drama will now come to an end; Osteotech's board unanimously approved the Medtronic acquisition, proving it is amenable to takeouts at the right price.

The deal will require approval of Osteotech's shareholders prior to closing. ■

Other News To Note

• **Cardio3 BioSciences SA**, of Mont-Saint-Guibert, Belgium, said key scientific data underlying its lead product C-Cure, a stem cell treatment for heart failure, has been published in the *Journal of the American College of Cardiology*. The research was carried out at Mayo Clinic, of Rochester, Minn., under a collaboration with the Cardiovascular Center in Aalst, Belgium.

• **Cryo-Cell International Inc.**, of Oldsmar, Fla., said it is collaborating with Monash University in Australia to conduct preclinical studies using Cryo-Cell's C'elle menstrual stem cell technology to identify potential future therapies to treat autoimmune diseases such as multiple sclerosis.

• **Cypress Bioscience Inc.**, of San Diego, said that its board sent a letter to Ramius LLC saying that its takeover offer "grossly undervalues" the company. Ramius' latest proposal is identical to the original proposal, with a purchase price of $4 per share in cash with a potential for a 50 percent retained interest in schizophrenia drug candidate BL-1020, Cypress said. (See *BioWorld Today*, July 10, 2010).

• **MabVax Therapeutics Inc**., of San Diego, has received a Small Business Innovation Research grant from the National Cancer Institute (NCI) under the agency's streamlined noncompeting award procedures (SNAP). Under the SNAP procedures, both initial and follow-on grant requests are submitted and evaluated as one request. The initial grant award of $150,000 goes to support the manufacture and testing of the company's sarcoma vaccine currently in clinical testing. The follow-on grant application, for more than $15 million, can be funded under fast-track procedures following normal NCI reporting and review procedures.

Chelsea

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While midodrine is an alpha agonist, Northera is a precursor drug to norepinephrine, he told *BioWorld Today*. Schwieterman noted that there is some evidence norepinephrine also has effects on cognition and concentration.

The FDA Monday said it was pursuing the withdrawal from the market of ProAmatine, which gained accelerated approval in 1996, and its generic equivalents because the makers of the drugs had failed to complete the required postmarketing studies to verify the clinical benefit of the medications.

A Shire spokeswoman, however, told *BioWorld Today* that the company had conducted and completed the postmarketing studies required under the accelerated approval commitment, but the FDA "viewed these trials as inconclusive," and called for additional trials. "This prompted Shire to explore other options," the spokeswoman said.

She stressed that Shire had notified the FDA in November 2009 and health professionals "earlier this year" that the Basingstoke, UK-based company planned to withdraw its new drug application for ProAmatine. Shire plans to cease sales of the drug by Sept. 30, the spokeswoman said, emphasizing that the withdrawal of ProAmatine was "not related" to any safety concerns of the medication.

She said Shire was not aware the FDA planned to issue its statement Monday on midodrines, and added that the firm believed the notice came in response to the company's communication last fall that the firm intended to remove ProAmatine from the market.

While the fate of Shire's drug may be sealed, the generic firms selling midodrine products – Apotex Corp., Impax Laboratories Inc., Mylan Pharmaceuticals, Sandoz Inc. and Upsher-Smith Laboratories – have 30 days to submit comments to the FDA, after which regulators will make a final determination.

No drug approved under the accelerated approval process has ever been pulled from the market due to a manufacturer not completing a required confirmatory study or when a follow-up trial has failed to confirm the medicine's clinical benefit. In fact, the Government Accountability Office (GAO) last year scolded the FDA for failing to use its authority to remove drugs whose makers had failed to follow through on their required postmarketing studies – specifically pointing out ProAmatine as one example. (See *BioWorld Today*, Oct. 27, 2009.)

The FDA had, however, restricted use of AstraZeneca plc's Iressa (gefitinib) to a subset of patients with non-small-cell lung cancer who already had taken the medicine and whose doctor believed it was helping them after the results of a follow-up trial in 1,700 patients indicated that the drug did not prolong survival.

The FDA currently is considering whether to revoke the accelerated approval for Avastin (bevacizumab), marketed by Genentech Inc. and its parent company Roche AG, as a treatment in combination with chemotherapy for HER2-negative metastatic breast cancer after follow-up studies failed to confirm the magnitude of improvement in progression-free survival observed in an earlier trial. (See *BioWorld Today*, July 19, 2010, and July 21, 2010.)

The FDA Monday indicated it was working with midodrine manufacturers to develop an expanded-access program that would allow patients to continue to receive the drug, although the details remain unclear.

But the loss of midodrine products from the orthostatic hypotension market may be Chelsea's gain – or at least investors thought so Tuesday, with shares of the biotech (NASDAQ:CHTP) gaining 34 cents, to close at $3.54.

While there are still other therapeutic options for NOH – the indication Chelsea, of Charlotte, N.C., is pursuing for Northera – "the elimination of a well-entrenched therapy would potentially enable greater share for droxidopa," said Oppenheimer & Co. analyst Brian Abrahams.

But most analysts remained cautious about whether Chelsea's Phase III program would demonstrate clear, statistically significant symptomatic improvements, given its mixed data reported so far.

The company last fall reported a higher-than-expected placebo response in its first Phase III study, known as 302 – an outcome that sent its shares spiraling down 61 percent and triggering a redesign of its second Phase III study, 301. (See *BioWorld Today*, Sept. 25, 2009.)

But Schwieterman noted that study 302 showed a benefit of Northera in the overall population, and in particular, patients with Parkinson's disease, "where we see the most dramatic benefits on our symptomatic and activities and daily living scores." He noted that the company expects to report results next month of study 301, which is investigating the drug in the same population as study 302: Parkinson's disease, multiple system atrophy and pure autonomic failure. "That also has a symptomatic functional outcome," Schwieterman said.

Study 301 is being conducted under a special protocol assessment agreement with the FDA.

Schwieterman noted that the measure used for the study is the Orthostatic Hypotension Questionnaire, which he said was a direct measure of patient symptomatic and activities of daily living benefit. "The whole cornerstone of our therapy is actually on symptomatic benefit," he insisted.

Chelsea's third Phase III trial of Northera in NOH, study 306, which is expected to report results in the second quarter of next year, is strictly in patients with Parkinson's disease, Schwieterman said.

Since Chelsea's trials already have a clinical benefit endpoint, as opposed to blood pressure only, and there is an SPA with the FDA for study 301, "we do not believe there is an increased regulatory hurdle for Northera and in fact we suspect the removal of midodrine could improve Northera's regulatory prospects," said Leerink Swann analyst Howard Liang. ■

Alzheimer's

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daily activities. Indianapolis-based Lilly said it will cease further dosing but will continue collecting safety data and cognitive scores in follow-up patient visits.

Nevertheless, it's another blow to Alzheimer's drug development and, possibly, to the theory that blocking or clearing amyloid beta is the way to combat the cognitive decline associated with the neurodegenerative disease. Although multiple studies have shown a correlation between the buildup of amyloid beta plaques and cognitive decline – and more than a few companies and investors have staked their claim to that research – skeptics have argued that amyloid beta plaques might simply be a symptom rather than a cause of Alzheimer's.

To date, late-stage data have done little to quash that skepticism. In addition to Flurizan, amyloid-targeting Alzhemed (tramiprosate) from Neurochem Inc. (now Bellus Health Ltd.) also failed to improve ratings on the Alzheimer's Disease Assessment Scale. Meanwhile, Phase III testing of bapineuzumab, a monoclonal antibody designed to clear amyloid beta plaques from Elan Corp. plc and Johnson & Johnson, is under way despite less than stellar Phase II data. (See *BioWorld Today*, July 31, 2008, and Aug. 28, 2007.)

Dublin, Ireland-based Elan shelved another Alzheimer's project, a synthetic amyloid beta peptide vaccine, after researchers reported that, despite being able to clear amyloid plaques, it failed to prevent progressive neurodegeneration and cognitive decline. (See *BioWorld Today*, July 18, 2008.)

And last year, researchers were thrown for a loop when mouse studies of Dimebon (latrepirdine) actually showed an increase in amyloid beta. The drug, which was believed to work by improving mitochondrial function in Alzheimer's patients, showed promising evidence of improving cognition in mid-stage trials but failed in a later Phase III study. (See *BioWorld Today*, March 4, 2010.)

The fact that semagacestat's data "suggested worsening cognitive outcomes raises questions about the utility of inhibiting amyloid beta for the treatment of Alzheimer's disease," Leerink Swann analyst Seamus Fernandez wrote in a research note. He also pointed to safety data showing that Lilly's drug was associated with an increased risk of skin cancer compared to placebo, which "may be related to either gamma secretase inhibition or off-target effects."

Still, amyloid beta continues to be the target du jour, and firms with earlier stage programs targeting gamma secretase won't be abandoning them simply because of the disappointing semagacestat trials.

Watertown, Mass.-based EnVivo Pharmaceuticals Inc., for instance, recently reported promising preclinical data with its gamma secretase modulator EVP-0015962, showing that its reduced amyloid plaque buildup in a transgenic mouse model. It also reversed behavioral deficits and reduced brain inflammation associated with Alzheimer's.

Elan is in Phase I with ELND006, another small-molecule gamma secretase inhibitor, and early stage firms such as Cognition Therapeutics Inc. and Archer Pharmaceuticals Inc. are in preclinical development with compounds targeting gamma secretase. ■

Other News To Note

· **Proteonomix Inc.**, of Mountainside, N.J., has executed a joint venture agreement with a group of investors that will create a new stem cell treatment and research facility in the United Arab Emirates. The investor group has committed to invest $5 million on or before Sept. 10. The joint venture company, XGen Medical LLC, will be owned 51 percent by Proteonomix and 49 percent by the investor group. Due to confidentiality and competitive reasons, the investor group has requested to remain anonymous for the present. The group is not related directly and/or indirectly to the company, its management, its board of directors or its current shareholders. The group assumes a variety of operational duties under the agreement, including some regulatory responsibility in the United Arab Emirates, physician recruitment and cooperative management of the local entity. The group's $5 million cash investment includes the purchase of $1 million of cellular material from Proteonomix. The agreement calls for Proteonomix, through its wholly owned subsidiary, StromaCel Inc., to receive $7,500 per treated patient. Additionally, the agreement calls for XGen, the joint venture, to market and distribute Proteoderm, including the Matrix NC-138 anti-aging products.

Fabrus

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The prevailing methods for discovering antibodies have been hybridoma antibody production and display technology. These technologies select the highest affinity antibodies. "I think in the last five years . . . it's been pretty clear that the highest affinity antibody isn't always the best therapeutic. That's one of the rationales for starting new technology," Smider said

High-affinity antagonist is a pretty narrow range of function compared to small-molecule therapeutics, which can have many different functions as agonists, partial agonists, antagonists and modulators.

"We thought there's really no reason antibodies can't have those activities," said Smider, adding that there are large classes of targets that have been refractory to antibody discovery, such as GPCRs and ion channels. Those types of proteins typically have several transmembrane domains, and it is difficult to raise antibodies to them by traditional methods because it is not possible to obtain purified protein in the proper folded state.

However, many cell-based assays are available for those proteins. Smider said the Fabrus platform allows it to make use of those technologies, avoiding the problem of purified membrane proteins.

Fabrus screens antibodies the way most companies screen small molecules. It has created a library of more than 10,000 pure human functional antibody (Fab) fragments, and is screening potential targets in functional assays against the library generates hits.

Smider told *BioWorld Today* that the technology is able to discover multiple antibodies against multiple targets. "We've actually got antibody hits against 12 targets in various stages of development," he said. "We're a small company, so we're not going to be able to develop 12."

Instead, Fabrus will work to license these excess leads to other companies, while developing others internally for oncology indications. For now, Smider declined to reveal details of how the company's platform works.

Fabrus founders spent the first two to three years inside the incubator developing the library and doing proof-of-concept studies. The company was ready to strike out on its own this year, and in January inked the documents that cut it loose from Pfizer's apron strings.

Fabrus moved to a new location in La Jolla to concentrate on growing the company. The first order of business is funding. Fabrus has recently closed on a round of bridge financing that Smider said is less than $1 million.

Pending additional investments and other business developments, the bridge round could close a second time and become a proper A financing round.

Pfizer retains equity in Fabrus, but has signed over control of the company to its founders.

The Pfizer Incubator opened in 2007 with 26,600 square feet of laboratory space and a budget of $12.5 million per year to divide among the five to eight companies occupying the space. (See *BioWorld Today*, March 19, 2007.) ■

Appointments And Advancements

• **Amarin Corp. plc**, of Dublin, Ireland, appointed Colin W. Stewart president, CEO and a member of the company's board, effective Aug. 16. Stewart has more than 30 years of experience in executive management and commercial positions for pharmaceutical companies, including five years as president and CEO of CollaGenex Pharmaceuticals Inc. where he was responsible for the company's growth leading to its successful sale in 2008.

• **CombiMatrix Corp.**, of Irvine, Calif., named Judd Jessup permanent CEO, effective Aug. 23. Jessup previously served as CEO of US Labs.

• **Selecta Biosciences Inc.**, of Watertown, Mass., appointed Werner Cautreels president and CEO. Cautreels most recently served as CEO and global head of R&D at Solvay Pharmaceuticals Inc., acquired earlier this year by Abbott, of Abbott Park, Ill. (See *BioWorld Today*, Sept. 29, 2009.)

Financings Roundup

• **MannKind Corp.**, of Valencia, Calif., said that in connection with its proposed offering of up to 8 million shares of its common stock, it will enter a share-lending agreement with Bank of America. Merrill Lynch, Pierce, Fenner & Smith Inc., an affiliate of Bank of America, is acting as sole book-running manager for the offering. Merrill Lynch intends to sell the borrowed shares in the common stock offering and use the resulting short position to facilitate short sales and privately negotiated derivative transactions by which the investors in a concurrent private offering of $100 million aggregate principal amount of MannKind's senior convertible notes due 2015 (or $115 million if the initial purchasers exercise their overallotment option in full) may hedge their investment in the notes. MannKind will not receive any proceeds from the offering, but will receive a nominal one-time loan fee. Bank of America will be required to return the borrowed shares pursuant to the terms of the lending agreement.