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Sharpens Orthopedic Focus

BioMimetic Scoring Again: \$40M For Dental Business

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West Coast Editor

Having proven the efficacy of its bone-graft product for the foot and ankle in a Canadian pivotal trial, BioMimetic Therapeutics Inc. is selling rights for the marketed periodontal therapy based on the same platform, thereby gaining \$40 million in cash that will be used for other product development.

The deal with partner Luitpold Pharmaceuticals Inc., disclosed Monday after the market closed, brings \$30 million to BioMimetic no later than 60 days after the papers are signed, then \$6 million within 18 months, and the rest due no later than the end of 2009.

Luitpold, a subsidiary of Tokyo-based Sankyo Co. Ltd., markets GEM 2IS through its Osteohealth division, and also is paying \$4 million in cash from the sale of existing inventory, plus royalty payments based on net sales of GEM 2IS and future products in the dental and cranio-maxillofacial field.

"It wasn't bringing a lot of revenue to us, and yet we and Luitpold remained extremely bullish on the technology," an attitude that is growing more than waning, said Samuel Lynch, BioMimetic's president and CEO. Luitpold will take over all of GEM 2IS activities, including downstream formulation, fill and finish manufacturing rights.

Approved by the FDA for bone loss and gingival recession associated with advanced periodontal disease in November 2005, GEM 2IS is based on the same platform as GEM OSI Bone Graft, which last week reported positive top-line results in a 60-patient, pivotal Canadian study, providing an 11 percent hike for BioMimetic's stock. The U.S. trial with GEM OSI, which combines platelet-derived growth factor with beta tricalcium phosphate, is expected to complete enrollment in mid-2008. (See *BioWorld Today*, Dec. 17, 2007.)

"We had been working on both events for a good por-

tion of the year," Lynch told *BioWorld Today*. "It's a bit fortuitous that they came out back to back, but not entirely," since Franklin, Tenn.-based BioMimetic "felt a lot more confident" after the Canadian data. "I wouldn't characterize it as a make-or-break situation," he added.

BioMimetic also has collected a time-based, \$5 million milestone payment for the second anniversary of the U.S. marketing approval for GEM 2IS, which also is sold in Canada, and stands to gain a \$10 million payment when the product is approved in Europe. GEM 2IS generated \$13 million in revenue for the third quarter, at the end of which the firm had \$68.3 million in cash, cash equivalents and short-term investments, according to the SEC quarterly filing.

Lynch said BioMimetic plans to sell GEM OSI in orthopedics itself, starting in foot and ankle fusion and then seeking a broader market, and will be calling on trauma surgeons, thanks to an apparent, unexpected benefit in tissue healing offered by the product.

The U.S. trial with GEM OSI started in April, comparing the product to autograft in foot and ankle fusions. Another study is under way in Europe. Surgeons perform more than 1 million procedures annually in the U.S. involving fusions (mainly in people with severe osteoarthritis) and corrective work. Indications covered in GEM OSI's trial program cover about 70,000 of those.

Shares of BioMimetic (NASDAQ:BMTI) closed Monday at \$15.99, up 74cents.

New York-based Boenning & Scattergood, which initiated coverage of BioMimetic earlier this year, maintained its "market outperform" rating on recently good news, and raised the price target from \$18 to \$20 in a December 14 research report. Deutsche Bank, also in New York, stayed with its "buy" rating Monday with a \$22 target. ■

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