Breaking News

INTERGEL Withdrawn from Market by Company

As posted on the IAS website at: www.adhesions.org/whatsnew.htm

Gynecare (division of Johnson & Johnson) have voluntarily withdrawn the anti-adhesion product - INTERGEL - from the market pending an investigation into the circumstances surrounding some adverse events including post-operative pain and inflammatory reaction. There were also two deaths where the product had been used after the accidental puncture of the bowel. The relationship between the product and these events is not certain, but the company are investigating it.

WHAT TO DO IF YOU THINK YOU HAVE HAD SIMILAR REACTIONS

The IAS has been contacted by a number of patients who have asked us what to do if they believe they have had a reaction to Intergel. Gynecare (a division of Johnson & Johnson - the marketers of the product) have kindly provided us with the following announcement:

"If you have had Intergel used during a surgical procedure and have any questions about it or believe you have had a reaction to it, you may contact Gynecare directly by dialing 877-384-4266, option 1. This number will connect you with a Registered Nurse who is trained to respond to your call."

You may also contact your own doctor who will make a report to the company, since this information will be useful to them in determining the cause. (If you do contact the company, let your doctor know this so that s/he can inform the company). You can let us know too if you wish.

For more information you can read the following press releases (PDF), as well as a copy of the letter sent to doctors (PDF) and the FDA Safety Alert.

GYNECARE Voluntarily Suspends Marketing and Sales of Anti-Adhesion Product Pending Evaluation of Postmarketing Events

CHASKA, Minn.--(BUSINESS WIRE)--March 27, 2003--LIFECORE BIOMEDICAL, INC. (Nasdaq:LCBM) announced today that GYNECARE has voluntarily suspended global marketing and sales of Lifecore's ferric hyaluronan adhesion prevention product, GYNECARE INTERGEL(a) Adhesion Prevention Solution ("INTERGEL Solution") and is voluntarily withdrawing the product from the market in order to assess information obtained from postmarketing experience with the device. The assessment will include a review of technical issues, surgical techniques, and circumstances associated with the postmarketing events, including reports from off-label use. Since the launch of the product in August of 1998 to February 2003, the worldwide complaint rate has been 0.29 percent of units sold. The contribution of the device to these events is unknown. Lifecore currently expects that such review will be conducted expeditiously and that the product will return to the market following completion of the review and implementation of any appropriate action.

INTERGEL Solution revenues accounted for 12 percent of Lifecore total revenues in fiscal year 2002 and have accounted for less than 10 percent of revenues in the current fiscal year. Terms of the Supply Agreement require payment for outstanding firm purchase orders which is expected to result in INTERGEL Solution revenue to Lifecore of approximately $1,100,000 for the quarter ending June 2003. Lifecore currently expects to reduce production levels during the quarter ending June 2003 which will result in unused manufacturing capacity charges of approximately $1,300,000.

Certain statements in this release are forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. Statements implying the successful outcome of the review of INTERGEL Solution post-marketing experience, the accuracy of the expected financial impact, or the likelihood of reintroduction and subsequent marketing success are subject to change. Because of numerous risks and uncertainties in the complex regulatory and competitive aspects of Lifecore's business activity, actual results may differ materially from those implied. Investors are strongly cautioned to review more detailed discussions

of those risks as presented in the Company's reports on Forms 10-Q and 10-K.

Lifecore Biomedical develops, manufactures, and markets biomaterials and medical devices for use in various surgical markets.

Additional general corporate information is available on the Internet at http://www.lifecore.com.

Lifecore Biomedical's conference call will begin today at 4:00 PM, Thursday, March 27, 2003. The replay will begin shortly after the completion of the live call. To access the telephone replay, call (719) 457-0820.

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Dow Jones Business News
Lifecore: Gynecare Suspends Anti-Adhesion Pdt Sales
Thursday March 27, 5:22 pm ET

CHASKA, Minn. (Dow Jones)--Lifecore Biomedical Inc. said its marketing partner Gynecare, the women's healthcare division of Ethicon Inc. (NYSE:JNJ - News) and a Johnson & Johnson company, voluntarily withdrew Gynecare Intergel from the market to assess information obtained from postmarketing experience with the product. Gynecare Intergel is a gel that prevents formation of internal scars after certain types of gynecological surgery.

In a press release Thursday, Lifecore said Gynecare has also voluntarily suspended global marketing and sales of the product.

Gynecare's assessment will include a review of technical issues, surgical techniques, and circumstances associated with the postmarketing events, including reports from off-label use.

The Food and Drug Administration initially rejected Gynecare Intergel in 2000 because it was deemed too risky. After Lifecore appealed, the product was approved in November 2001. Upon approval, the FDA called use of Intergel " reasonably safe," and provided surgeons with a list of restrictions about how it should be used.

From the launch of the product in August 1998 to February 2003, the worldwide complaint rate has been 0.29% of units sold, Lifecore said, while the contribution of the device to these events is unknown.

Lifecore currently expects the review to be conducted expeditiously and the product to return to the market once the review is completed and any appropriate actions are taken.

Intergel revenue accounted for 12% of Lifecore's total revenue of $38.8 million in fiscal 2002 and has accounted for less than 10% of revenue in the current fiscal year, which ends in June.

Lifecore expects Intergel revenue of about $1.1 million in the fourth quarter, as terms of its supply agreement require payment for outstanding firm purchase orders. Lifecore expects, however, to cut fourth-quarter production levels, which will result in unused manufacturing capacity charges of about $1.3 million.

In after-hours trading, Lifecore's shares recently traded at $3.99, according to the Island ECN (News - Websites), down sharply from their regular Nasdaq session close of $ 6.09.

Company Web site: http://www.lifecore.com

-Stephen Lee; Dow Jones Newswires; 201-938-5400

Dow Jones Business News
Lifecore/Gynecare Intergel: FDA Approved In Nov 2001
Thursday March 27, 5:20 pm ET

The Food and Drug Administration initially rejected Gynecare Intergel in 2000 because it was deemed too risky. After Lifecore appealed, the product was approved in November 2001. Upon approval, the FDA called use of Intergel " reasonably safe," and provided surgeons with a list of restrictions about how it should be used.

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-Stephen Lee; Dow Jones Newswires; 201-938-5400
A Johnson & Johnson spokeswoman said the voluntary suspension of Gynecare Intergel won't have a material impact on its financial results. The company has a policy of not disclosing sales by product or product category.
The spokeswoman said incidents of postmarket experience related to the use of Intergel include repeat

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http://www.startribune.com/stories/535/3787308.html
Lifecore Biomedical suspends sales of Intergel
Terry Fiedler, Star Tribune

Published March 28, 2003 LCBM28

Chaska-based Lifecore Biomedical Inc. has suspended sales of its gynecological surgical gel, a product that accounts for about 10 percent of its sales and much of the investor interest in the company.
The move, announced late Thursday, was prompted not by the Food and Drug Administration (FDA) but by the gel's worldwide distributor, medical giant Johnson & Johnson, which wanted the product pulled while it studied some of its possible side effects, especially in off-label uses.
"This is perplexing. I've never run into anything like this," said U.S. Bancorp Piper Jaffray analyst Thomas Gunderson. "The unfortunate part is that [Johnson & Johnson] is not talking or letting a lot of information be released."
Lifecore CEO Jim Bracke wouldn't comment on how long the review process might take, but Gunderson estimated that the product, called Intergel, could be off of the market for six months to a year.
Gunderson said that Lifecore stock, which was down 2 percent to $6.09 a share Thursday, figures to be under pressure today as investors react to the news announced after the market closed.
Intergel was in use, but not specifically tied to two deaths of people who had punctured bowels, Bracke said, adding that most clinicians would cite the punctured bowel as the probable cause of death. Other potential side effects of Intergel included pain and inflammation, he said.
Bracke said he found Johnson & Johnson's unilateral decision "quite surprising," adding that the FDA was "perfectly comfortable" with the product performance. Lifecore estimated that its worldwide complaint rate on the product to be 0.29 percent of units sold.
On a spectrum of actions that could be taken, he called the product withdrawal "on the most extreme conservative side of that."
At the same time, Bracke said he is confident that Johnson & Johnson was not trying to whipsaw the company for some financial advantage but simply was assuring that a one-of-a-kind product isn't somehow jeopardized by future regulatory problems.
Intergel, which the FDA approved for sale in the latter part of 2001, is used to help heal wounds caused by gynecological surgery. Without treatment, those wounds can heal improperly, causing internal scars called adhesions that can be painful and lead to infertility or bowel obstructions.
The gel is approved for use in open gynecological surgery but also is used in less-invasive procedures and for certain intestine-related procedures..
Although the company gets the bulk of its annual sales of about $40 million from dental implants and other dental products, Intergel has drawn the most investor attention because it was projected to be a dominant player in a possible $500 million market.
The company isn't modifying earnings projections for the quarter that ends this month but will take $1.3 million in charges in the quarter ending in June for unused manufacturing capacity.
Terry Fiedler is at tfiedler@startribune.com.
