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STREET WISE

By Amy Tsao

Why Inamed Is All Pumped Up

Shares of the beauty-treatment maker are surging as the company aims to bring silicone implants back to the marketplace

Sagging breasts, wrinkled faces, flabby bodies: These are the complaints from which Inamed Corp. has made its fortunes. The Santa Barbara (Calif.)-based company is one of two makers of saline breast implants in the U.S. and also sells collagen products and an antiobesity device that limits food intake.

Focusing largely on beauty treatments has helped Inamed (IMDC) make a pretty penny. In the past year, sales for all of Inamed's businesses have risen despite the difficult economy. Revenues in the quarter ended June 30 rose 20%, to \$85.8 million, and net profits increased 56%, to \$12.8 million, from the same period a year ago. Investors have sure noticed. The stock has soared from \$20 to a high of \$71 per share in the past 52 weeks. It closed at \$69 on Aug. 25.

The recent run-up can be attributed, in part, to the possibility of Food & Drug Administration approval in 2004 for expanding the use of silicone implants in cosmetic breast augmentation. In 1992, the FDA restricted the use of silicone for women who have lost breasts to cancer or who need replacements for implants that are leaking or must be replaced for other reasons. The controversy still rages over whether silicone implants can cause cancer and other diseases in women. An FDA-appointed panel of experts will review Inamed's new application in mid-October. The panel will then likely issue a final recommendation to the FDA -- which generally follows the advice of its panels.

BOOMING MARKET. If Inamed gets the nod, it could provide a big boost to its already healthy implant business, which comprises both the saline variety and limited-purpose silicone and is the company's biggest source of revenues. Breast implants accounted for \$156.2 million, or 57% of total revenues of \$275.7 million in 2002.

"I think if silicone implants are approved, Inamed's growth would accelerate," says Jayson Bedford, analyst at Adams, Harkness & Hill, noting overall sales have been growing about 10% to 12% annually over the last several years. He has a 52-week price target on the stock of \$73. (Bedford does not personally own shares, but his firm is seeking to do investment banking with Inamed and Mentor (MNT), Inamed's main rival.)

Another potential plus: If Inamed's application is approved, it will likely get its silicone implants to the consumer market well in advance of Mentor, which is about one year behind in submitting its application. In such a scenario, CIBC World Markets analyst John Calgagnini figures Inamed would dominate the market, adding "incremental sales of \$50 million to \$100 million, which would translate into an estimated \$10 million to \$20 million in incremental earnings." These figures don't even take into account the somewhat higher margins that Inamed should be able to charge for silicone vs. saline, Calgagnini writes. (CIBC makes a market in Inamed shares and the firm expects to receive investment-banking fees from Inamed in the next three months.)

UGLY HISTORY. Many plastic surgeons are hopeful that American women considering implants will still go for silicone because it's regarded as the more aesthetically pleasing option. In countries where both are available, women choose silicone far more frequently than saline. "Once available, there will clearly be women interested in having them placed," says Dr. Kenneth Shestak, chief of plastic surgery at Magee Women's hospital and associate professor at the University of Pittsburgh. (Shestak is testing products made by both Mentor and Inamed.)

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While the rally in Inamed stock suggests market optimism that its implants have a clear path to the market, there could be more controversy to come. For one, the National Organization for Women (NOW) is urging the FDA to take its time allowing silicone back onto the market. It recommends that the FDA ask manufacturers to provide more than the two years to three years of follow-up data currently being requested.

Indeed, the history of silicone implants is far from pretty. Beginning in the early 1980s, reports of dangers related to silicone implants led to a litany of law suits. Major makers like Dow Corning and Bristol-Myers Squibb (BMY) discontinued making them and the cost of litigation helped lead to a bankruptcy filing by Dow Corning in 1998.

DUELLING REPORTS. The results of scientific studies have been mixed -- and some say misinterpreted. Plastic surgeons and manufacturers cite an Institute of Medicine (IOM) report released in 1999 that concluded silicone implants don't cause systemic diseases including cancer and autoimmune diseases like lupus or rheumatoid arthritis. The IOM report reviewed thousands of studies of silicone implants.

Yet others have questioned the scientific soundness of the IOM report, pointing to more recent studies that raise doubts. Dr. Diana Zuckerman, president of the National Center for Policy Research for Women & Families, a nonprofit think tank, says many of the studies included in the IOM report weren't well-designed and patients weren't tracked for sufficient periods.

Separately, a study carried out by the National Cancer Institute, released in 2001, showed a higher rate of brain cancer in women with silicone implants. Another NCI study, looking at causes of death among silicone-implant recipients, showed a higher rate of death from lung cancer, emphysema, and suicide compared with women who received other plastic-surgery procedures.

MIXED MESSAGES. While both silicone and saline breast implants are prone to deflation, rupturing, and hardening, silicone ruptures can often go undetected while saline ruptures are immediately noticeable. A separate FDA report released in 2001 revealed troubling results related to ruptures, Zuckerman says. In a study of women who had silicone implants for at least six years and who were healthy and reported no problems with their implants, MRI scans showed that 20% of the implants were leaking. And the women who had the leaks were more likely to have fibromyalgia and other autoimmune diseases than those who did not experience leaks.

Efforts by groups like NOW will add pressure to the FDA approval panel, says Adina Dodi, analyst at B. Riley & Co. And there is the chance that Inamed's filing won't meet FDA muster anyhow, she adds. "[Approval is] not a certainty," she says. However, Dodi, who rates Inamed stock neutral on valuation, expects that the company would not have submitted its application if it didn't have sufficient information. (Dodi does not own the stock and her firm does not do any investment banking for Inamed.)

Even if Inamed gets approval, marketing could be a problem. Some surgeons think that at least initially, a sizable percentage of women considering implants may choose saline, despite the more flesh-like qualities of silicone. Dr. Michael Byun, plastic surgeon and the director of Chicago Cosmetic Surgery, says that about half of his patients who are qualified to get silicone implants opt for saline "because of that phobia" of increasing the risk of cancer or rheumatoid arthritis or lupus.

TUMMY TIGHTENER. Even if its silicone plans go bust for one reason or another, Inamed could still be a long-term winner, thanks to the American obsession with the perfect body. The market for breast augmentation is expected to grow steadily, with or without the option of silicone. And demand is growing outside the U.S., too. Worldwide sales for implants are growing at about 10% a year and show no signs of slowing. Sales of Inamed's LapBand, a gastric band that makes wearers feel full on significantly smaller quantities of food, jumped 59%, to \$15 million in the most recent quarter. Demand should remain robust, as more and more overweight Americans yearn for slimmer bodies.

Revenues from collagen and other facial-rejuvenation products rose 14%, to \$22 million. A competing product to Allergan's (AGN) hit Botox treatment and a new wrinkle filler are anticipated to receive FDA approval over the next two years (see BW Online, 5/08/03, "The New Face of Anti-Aging Treatments").

Ultimately, Americans' obsessions with their looks, looks like good news for Inamed.

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