



BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, Illinois 60069  
www.biosantepharma.com

---

FOR IMMEDIATE RELEASE

Amex: BPA

## **BioSante Announces Study Shows LibiGel™ (transdermal testosterone gel) Significantly Increases Sexual Activity in Menopausal Women**

### **Women in Study Reported 238% Increase in Frequency of Satisfying Sexual Events**

**LINCOLNSHIRE, Illinois (September 22, 2004)** – BioSante Pharmaceuticals, Inc. (Amex: BPA) announced today that data from its placebo-controlled Phase II study showed treatment with LibiGel™, an investigational transdermal testosterone gel, significantly increased satisfying sexual activity in surgically menopausal women suffering from female sexual dysfunction (FSD). Study results will be presented by BioSante in an oral Podium Session on October 30, 2004 at the Annual Meeting of the International Society for the Study of Sexual Health in Women (ISSWSH) in Atlanta.

Study results showed an effective dose of LibiGel that significantly increased the number of satisfying sexual events by 238 percent versus baseline ( $p < 0.0001$ ); this increase also was significant versus placebo ( $p < 0.05$ ). The effective dose of LibiGel produced testosterone blood levels within the normal range for pre-menopausal women and had a safety profile similar to that observed in the placebo group. No serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel, indicating the safety and acceptability of LibiGel. The study was a double-blind, placebo-controlled study, conducted in the United States, that included 46 surgically menopausal women distressed by their low sexual desire and activity.

“The LibiGel data are very positive and point to the development of a safe and effective treatment for women with the low sexual desire component of FSD, also known as Hypoactive Sexual Desire Disorder (HSDD),” said Dr. Leah M. Lehman, vice president of clinical and regulatory affairs for BioSante. “The study results indicate LibiGel is more effective than other testosterone products being developed, which may be a function of our formulation and dosing regimen.”

“The LibiGel data are very exciting for physicians who treat menopausal women. We know there is a tremendous medical need to address women suffering with low sexual desire,” said James A. Simon, MD, lead study investigator, Clinical Professor of Obstetrics and Gynecology at the George Washington University in Washington, D.C., Medical Director at The Women’s Health Research Center in Laurel, Maryland and president of the North American Menopause Society. “Currently, there are no medications approved by the U.S. Food and Drug Administration for the treatment of low sexual desire, so we’re encouraged by such clinically significant improvements in sexual activity, resulting from treatment with LibiGel. We are hopeful that treatments like LibiGel will help women with low sexual desire regain a satisfying sex life.”

“These extremely encouraging clinical data show that LibiGel improves sexual activity in women suffering from HSDD, and we believe that LibiGel can make an important contribution to the well-being of women,” said Stephen M. Simes, president and chief executive officer of BioSante.

-more-

"Female sexual dysfunction is underserved by the pharmaceutical industry today; in fact, there is no pharmaceutical product on the market for the treatment of FSD. We are very pleased LibiGel may help successfully address this unmet medical need. Planning for Phase III development of LibiGel is in progress, and we plan to initiate Phase III trials early in 2005."

LibiGel is a gel formulation of bioidentical testosterone designed to be quickly absorbed through the skin after application on the arms, shoulders or abdomen, delivering testosterone to the bloodstream evenly over time and in a non-invasive and painless manner. Though generally characterized as a male hormone, testosterone also is present in women and its deficiency has been found to decrease libido or sex drive. Studies have further shown that testosterone therapy can increase bone density, raise energy levels and improve mood, in addition to boosting sexual desire and activity.

According to a study published in the *Journal of the American Medical Association*, 43 percent of American women (about 40 million) experience some degree of impaired sexual function. Among the more than 1,400 women surveyed, 32 percent lacked interest in sex and 26 percent could not experience orgasm. The majority of women with FSD are postmenopausal, experiencing FSD due to hormonal changes following menopause, whether natural or surgical.

#### ***BioSante's hormone product portfolio***

In addition to LibiGel, BioSante is developing Bio-T-Gel™ for treatment of men with testosterone deficiency and Bio-E-Gel™ for treatment of women with estrogen deficiency. Symptoms of these hormone deficiencies in men include impotence, diminished sex drive, muscle weakness and osteoporosis. Symptoms in menopausal women include hot flashes, vaginal atrophy, decreased libido and osteoporosis. The transdermal gel formulations used in the female gel products are licensed by BioSante from Antares Pharma Inc. The estrogen and testosterone markets in the United States alone account for approximately \$2.5 billion in annual sales.

#### ***About BioSante Pharmaceuticals, Inc.***

BioSante is developing a pipeline of hormone therapy products to treat both men and women. BioSante's hormone therapy products are gel formulations for transdermal administration that deliver bioidentical estradiol and testosterone. The company also is developing its calcium phosphate nanotechnology (CAP) for novel vaccines, including biodefense vaccines for toxins such as anthrax and ricin, and drug delivery systems. Additional information is available online at [www.biosantepharma.com](http://www.biosantepharma.com).

*This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The statements regarding BioSante contained in this press release that are not historical in nature, particularly those that utilize terminology such as "may," "will," "should," "likely," "expects," "anticipates," "estimates," "believes" or "plans," or comparable terminology, are forward-looking statements. Forward-looking statements are based on current expectations and assumptions, and entail various risks and uncertainties that could cause actual results to differ materially from those expressed in such forward-looking statements. Important factors known to BioSante that cause actual results to differ materially from those expressed in such forward-looking statements are the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance, and other factors identified and discussed from time to time in BioSante's filings with the Securities and Exchange Commission, including those factors discussed on pages 18 to 25 of BioSante's Form 10-KSB, which discussion also is incorporated herein by reference.*

#### **For more information, please contact:**

Ritu S. Baral

The Trout Group LLC

212-477-9007 ext 25; rbaral@troutgroup.com

Phillip B. Donenberg, CFO, BioSante

847-478-0500 ext 101

donenber@biosantepharma.com

###