# BioSante Pharmaceuticals Announces Positive LibiGel® Pharmacokinetic Study Results

**LINCOLNSHIRE, Illinois (November 16, 2011)** - BioSante Pharmaceuticals, Inc. (NASDAQ: BPAX), today announced additional results from its principal LibiGel (testosterone gel) pharmacokinetic (pK) study. Top line data from this study were announced on September 12, 2011. The pK study results indicate that LibiGel increases levels of free testosterone (the active testosterone component) in the serum of postmenopausal women to within the normal ranges for younger, premenopausal women. LibiGel is in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in postmenopausal women, for which there is no FDA-approved product.

The pK study was conducted in 24 surgically postmenopausal subjects in three contiguous 21 day periods for a total of 63 days, in the absence of estrogen therapy (study period 1), with a concomitant transdermal estradiol patch (study period 2) and finally with concomitant oral estrogen (study period 3). LibiGel was dosed at 0.22 grams daily, the same dose as included in the two LibiGel pivotal safety and efficacy trials and safety study. The mean free testosterone level at baseline was 1.4 pg/ml. During the study, subjects in the pK study demonstrated a mean free testosterone of approximately 3.5 pg/ml on day 14, and 4.1 pg/ml on day 21 (at the end of study period 1) and approximately 4.5 pg/ml on study day 42 (at the end of 21 days of transdermal estradiol co-therapy in period 2). During study period 3, the mean free testosterone level was approximately 3.7 pg/ml. Free testosterone returned to baseline levels within 24 hours after the last dose of LibiGel, indicating effective elimination after dosing is discontinued.

The levels of free testosterone in the LibiGel pK study were similar to those seen in the BioSante LibiGel Phase II efficacy trial which ranged from 2.8 pg/ml to 3.6 pg/ml. These levels also were similar to those reported in the two pivotal testosterone patch (Intrinsa) studies which showed efficacy in treating HSDD in estrogen-treated surgically menopausal women, which were 4.0 pg/ml at 12 weeks and 3.1 pg/ml at week 24 and 4.0 pg/ml at week 24, respectively. In a recent publication, it was shown that serum testosterone concentrations in normally cycling 30-year-old pre-menopausal women range from 1.2 pg/ml to 6.4 pg/ml. However, generally, blood levels are not compared between studies because different studies performed at different times with different assays can produce varying testosterone blood levels.

| | "Normal" 30-year-old premenopausal women | LibiGel pK Study: Baseline | LibiGel pK Study: Day 14 | LibiGel pK Study: Day 21 | LibiGel pK Study: Day 42 | LibiGel pK Study: Day 63 |
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| Mean Free Testosterone | 1.2 - 6.4 pg/ml | 1.4 pg/ml | 3.5 pg/ml | 4.1 pg/ml | 4.5 pg/ml | 3.7 pg/ml |

| | "Normal" 30-year-old premenopausal women | Intrinsa Efficacy Study: Week 12 | Intrinsa Efficacy Study: Week 24 |
|---|---|---|---|
| Mean Free Testosterone | 1.2 - 6.4 pg/ml | 4.0 pg/ml | 3.1 pg/ml / 4.0 pg/ml |

In the LibiGel Phase III clinical studies, baseline testosterone levels, although collected, are not an inclusion or exclusion criterion, per FDA suggestion, since therapy for HSDD is meant for symptomatic treatment of HSDD and not testosterone levels. BioSante plans to present the full

pK study results at an upcoming medical meeting. The LibiGel pK study was conducted as part of the FDA-requested studies to be submitted in the LibiGel new drug application (NDA) which is anticipated in the fourth quarter of 2012.

**About LibiGel®**

LibiGel is a testosterone gel in Phase III clinical development for the treatment of women who suffer from female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD). The completed Phase III efficacy trials are double-blind, placebo-controlled trials that enrolled over 500 surgically menopausal women each for six-months of therapy, approximately half of whom were taking concomitant estrogen therapy and half of whom took no concomitant estrogen therapy. The completed efficacy trials were conducted according to an FDA-agreed special protocol assessment (SPA) agreement. LibiGel is absorbed quickly through the skin after applying a once-daily pea-sized topical application on the upper arm that delivers testosterone to the bloodstream evenly over time.

In addition, BioSante is conducting the Phase III LibiGel safety study, a randomized, double-blind, placebo-controlled, multi-center, cardiovascular (CV) events and breast cancer study that has completed enrollment of 3,656 women and has accrued over 5,100 women-years of exposure, to date. The study will continue for a total of five years; however, BioSante will use the safety study data as part of an NDA submission after the last subject enrolled has completed 12 months of exposure to LibiGel or placebo.

The LibiGel safety study is tracking a predefined list of CV events, in agreement with the FDA, including CV death, myocardial infarction and stroke in women 50 years of age or older and suffering from at least two CV risk factors including hypertension and diabetes. The objective of the safety study is to demonstrate the relative safety of testosterone compared to placebo in the number of CV events. The incidence of breast cancer also is being tracked over the course of the study. The study represents the largest data base of the safety of testosterone in women.

Upon completion of the statistical analyses of efficacy trials and the safety study, BioSante intends to submit an NDA to the FDA, requesting approval of LibiGel for the treatment of HSDD in menopausal women. The NDA submission is targeted for the fourth quarter of 2012.

**About BioSante Pharmaceuticals, Inc.**

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. BioSante's lead products include LibiGel® (transdermal testosterone gel) for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD), which is in Phase III clinical development according to a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA). BioSante's first FDA-approved product is Elestrin™ (estradiol gel) indicated for the treatment of hot flashes associated with menopause, marketed in the U.S. by Azur Pharma, BioSante's licensee. BioSante also is developing a portfolio of cancer vaccines, four of which have been granted Orphan Drug designation, and are currently in several Phase II clinical trials. Other BioSante products are Bio-T-Gel™, a testosterone gel for male hypogonadism, for which an NDA is pending, licensed to Teva Pharmaceuticals, and an oral contraceptive in Phase II clinical development. Additional information is available online at:

http://www.biosantepharma.com

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***Forward-Looking Statements***

*To the extent any statements made in this news release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about BioSante's plans, objectives, expectations and intentions with respect to future operations and products, the timing of anticipated regulatory submissions and other statements identified by words such as "will," "continue," "could," "believe," "intends," "continue," "expects," "anticipates," "estimates," "may," other words of similar meaning, derivations of such words or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause BioSante's actual results to be materially different than those expressed in or implied by BioSante's forward-looking statements. For BioSante, particular uncertainties and risks include, among others, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; the marketing success of BioSante's licensees or sublicensees; the success of clinical testing; and BioSante's need for and ability to obtain additional financing. More detailed information on these and additional factors that could affect BioSante's actual results are described in BioSante's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and subsequent quarterly report on Form 10-Q. All forward-looking statements in this news release speak only as of the date of this news release. BioSante undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.*