



# LibiGel<sup>®</sup>

(Testosterone Gel)

LibiGel<sup>®</sup> - transdermal testosterone gel in development for the treatment of female sexual dysfunction (FSD)

## LibiGel<sup>®</sup>\* Treatment of Women with Hypoactive Sexual Desire Disorder (HSDD)

LibiGel<sup>®</sup> is a gel formulation of testosterone in development that is quickly absorbed through the skin after a once-daily application of a pea-sized dose of gel on the upper arm, 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. In addition, studies have shown that testosterone therapy can increase bone density, raise energy levels and improve mood, in addition to boosting sexual desire and activity.

\* Product in clinical development and is not FDA approved

## Therapeutic Indication

**Hypoactive Sexual Desire Disorder (HSDD) – lack of sexual desire – affects millions of women in the U.S., especially those past menopause, whether natural or surgical. Studies find it is more common than erectile dysfunction – which is a \$2 billion a year prescription business in the U.S. A University of Chicago study of 1,700 men and 1,700 women between the ages of 18 and 59 published in JAMA, found that 43% of women said they have experienced some degree of sexual dysfunction, compared with just 31% of men. Among the women surveyed, 32% lacked interest in sex. Further, according to a study published in the NEJM, 43% of women between the ages of 57 and 85 experience some degree of low sexual desire. The majority of women with FSD are postmenopausal, experiencing FSD due to hormonal changes following menopause, whether natural or surgical. In 2009, there were over 4.0 million testosterone prescriptions written off-label for the treatment of HSDD. Over 90% of women using testosterone off-label would be switched to LibiGel<sup>®</sup> once approved, according to surveyed physicians.**

## Unmet Clinical Need / Market Opportunity

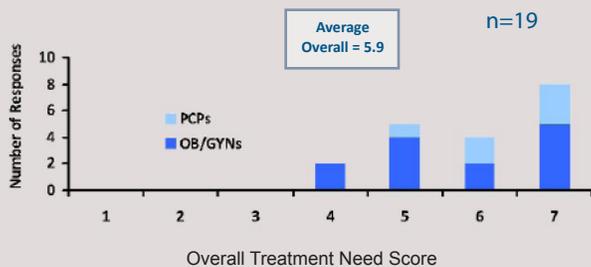
The goal of testosterone treatment of women experiencing Hypoactive Sexual Desire Disorder (HSDD) is to increase the serum testosterone towards the normal range of premenopausal women in an effort to alleviate the symptoms of this disorder. Although there are a number of FDA approved products available for erectile dysfunction, in the U.S., there are no FDA approved drug therapies for the treatment of HSDD in women.

In research conducted by Campbell Alliance, a premier pharmaceutical consulting firm, physicians reported a high level of need for an effective, safe and FDA approved product for HSDD.

This market has wide potential with predictions ranging from about \$2.0 billion up to \$5 billion. The \$2.0 billion potential is the size of the male market if one considers only the current erectile dysfunction products. The current market for testosterone products for men is an additional \$1 billion and growing.

And according to IMS and other data, in 2009 over four million “off label” prescriptions were written for women in the U.S. According to survey data, clinicians indicated that they would prefer to prescribe an FDA approved product that has been clinically tested and proven to be safe and effective for the treatment of HSDD, and they would switch over 90% of their patients using testosterone to LibiGel<sup>®</sup>. In addition, the physicians indicated the number of women using testosterone for HSDD would more than double given an FDA approved product.

### High Unmet Need - Desire for Pharmaceutical Treatment Options



Rating is based on a 1 to 7 scale, with “1” being low need and “7” being high need.

Source: Results of 20 interviews (15 OB-GYN, 5 PCP) conducted by Campbell Alliance in February and March 2010. Note: One physician did not respond to this question.

## Competition

In the U.S., no drug ever has been approved for the treatment of female sexual dysfunction, specifically HSDD, notwithstanding the fact that erectile dysfunction drugs for men were approved over 12 years ago. BioSante believes that LibiGel can be the first FDA approved pharmaceutical product for the treatment of HSDD in menopausal women, an important unmet medical need.

## Regulatory Status

The LibiGel clinical development program, in consultation and agreement with the FDA, has been designed to show that LibiGel can safely improve women’s sexual desire and the frequency of satisfying sexual events and decrease personal distress associated with low sexual desire in women with HSDD. BioSante is conducting three Phase III LibiGel clinical studies and BioSante’s objective is to submit a new drug application (NDA) to the FDA in 2011 for a potential approval in 2012.



**Results of Phase II:** Specifically to testosterone and LibiGel in the treatment of female sexual dysfunction, there is little question that testosterone can increase the number of satisfying sexual events, the FDA's primary endpoint for approval of a drug for this indication. Both BioSante and Proctor & Gamble (for their testosterone patch, Intrinsa, which is not currently in active clinical development and now owned by Warner Chilcott) have completed clinical trials showing the efficacy of testosterone to statistically and clinically significantly increase the number of satisfying sexual events.

Treatment with LibiGel in BioSante's Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD. The Phase II trial results showed LibiGel significantly increased the number of satisfying sexual events by 238% versus baseline ( $p < 0.0001$ ); this increase also was significant versus placebo ( $p < 0.05$ ). In this study, the effective dose of LibiGel produced testosterone blood levels within the normal range for premenopausal women and had a safety profile similar to that observed in the placebo group. In addition, no serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel. The Phase II clinical trial was a double-blind, placebo-controlled trial, conducted in the U.S., in surgically menopausal women distressed by their low sexual desire and activity.

**Progress and Plans in Phase III:** Currently, BioSante is conducting three Phase III clinical studies to demonstrate the safety and efficacy of LibiGel to increase sexual desire and satisfying sexual events and to decrease distress associated with the decreased desire. Two Phase III safety and efficacy trials that are underway are randomized, double-blind, placebo-controlled trials which will enroll approximately 500 surgically menopausal women each for six-months of treatment. BioSante is conducting these trials under an FDA agreed special protocol assessment (SPA). In addition, BioSante has another SPA agreement with the FDA related to treatment of naturally menopausal women. The SPA process and agreement confirms the FDA's position that FSD and HSDD are true conditions that women experience, with measurable endpoints, that can be evaluated and which deserve therapeutic options. It also affirms that the FDA agrees that the LibiGel Phase III safety and efficacy clinical trial design, clinical endpoints, sample size, planned conduct and statistical analyses are acceptable to support regulatory approval. Further, it provides assurance that these agreed measures will serve as the basis for regulatory review and the decision by the FDA to approve an NDA for LibiGel.

In addition to the two Phase III safety and efficacy trials covered by the SPA, BioSante is conducting one Phase III cardiovascular and breast cancer safety study of LibiGel, which also is underway. The safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events and breast cancer study of between 2,750 and 4,000 women exposed to LibiGel or placebo. BioSante will follow the women enrolled in the safety study for a total of 5 years. However, after an average of 12 months' exposure BioSante intends to submit a LibiGel NDA for review and potential approval by FDA.

The LibiGel safety study is tracking a composite of cardiovascular events including cardiovascular death, myocardial infarction and stroke in women with FSD who are 50 years of age or older and have at least two cardiovascular risk factors such as hypertension and diabetes. The objective of the safety study is to show the relative safety of testosterone compared to placebo in the number of cardiovascular events. The incidence of breast cancer also will be tracked throughout the study.

BioSante has reported that in the first 2,750 women enrolled comprising approximately 2,700 women-years of exposure, there have been only 14 adjudicated cardiovascular events even though the safety study is enrolling women with a higher risk of cardiovascular events. To date, over 2,750 women have been enrolled.

BioSante's objective is to submit the LibiGel NDA in 2011 for a potential FDA approval in 2012.

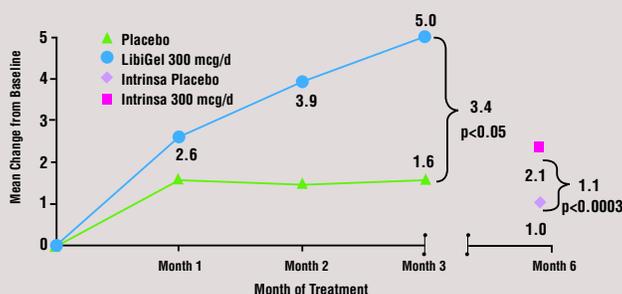
## Comparative Results

|  | BioSante/<br>LibiGel                       | P&G/<br>Intrinsa                             | P&G/<br>Intrinsa                             |
|--|--|--|--|
| Study Design                             | 3 month Phase II<br>300 mcg/day<br>N=46 SM | 6 month Phase III<br>300 mcg/day<br>N=562 SM | 6 month Phase III<br>300 mcg/day<br>N=533 SM |
| % increase in sexual event from baseline | 238%*                                      | 74%*   | 51%*   |
| # increase active v. placebo             | 5.0 v. 1.6*                                | 2.13 v. 0.98*                                | 1.56 v. 0.73*                                |
| Application site reactions               | rare                                       | ~ 30%  | ~ 30%  |

\*Statistically significant versus baseline and placebo, respectively  
SM = surgically menopausal

## LibiGel® vs. Intrinsa®

Mean change from baseline in 4-week satisfying sexual event rate  
Estrogen-treated woman



## About BioSante Pharmaceuticals, Inc. (NASDAQ: BPAX)

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) which is in Phase III clinical development under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA), and Elestrin™ (estradiol gel) for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, which is 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 FDA Orphan Drug designation, and are currently in several Phase II clinical trials. Other products in development are Bio-T-Gel™, a testosterone gel for male hypogonadism, licensed to Teva Pharmaceuticals and an oral contraceptive in Phase II clinical development using BioSante patented technology. The company also is seeking opportunities for its other technologies.

*This brochure may contain forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include statements about BioSante's plans, objectives, expectations and intentions with respect to future operations and products, future market acceptance, size and potential of LibiGel and other statements identified by words such as "will," "potential," "could," "would," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," other words of similar meaning 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 reports on Form 10-Q. All forward-looking statements in this brochure speak only as of the date of this brochure. BioSante undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.*

For more information about LibiGel®, please contact:

BioSante Pharmaceuticals, Inc.

111 Barclay Boulevard

Lincolnshire, Illinois 60069

Phone: 847-478-0500

Fax: 847-478-9152

[www.biosantepharmaceutical.com](http://www.biosantepharmaceutical.com)