# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 8-K

**Current Report**
**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported):
**January 10, 2011**

# BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-31812** | **58-2301143** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (I.R.S. Employer Identification Number) |

| **111 Barclay Boulevard**<br>**Lincolnshire, Illinois** | **60069** |
|---|---|
| (Address of Principal Executive Offices) | (Zip Code) |

**(847) 478-0500**
(Registrant's Telephone Number, Including Area Code)

**N/A**
(Former Name or Former Address, If Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Section 7 — Regulation FD**

**Item 7.01. Regulation FD Disclosure**

Beginning on or shortly after January 10, 2011, representatives of BioSante Pharmaceuticals, Inc. ("BioSante") intend to make presentations at investor conferences and in other forums and distribute an informational presentation to interested persons, which presentations may include the information contained in Exhibit 99.1 and Exhibit 99.2 attached to this current report on Form 8-K. BioSante is furnishing the information contained in Exhibit 99.1 and Exhibit 99.2 pursuant to Regulation FD. This information is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing unde r the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing. BioSante expects to disclose this information, in whole or in part, and possibly with updates and modifications, in connection with presentations to investors, analysts and others.

The information contained in Exhibit 99.1 and Exhibit 99.2 is summary information that is intended to be considered in the context of BioSante's Securities and Exchange Commission ("SEC") filings and other public announcements that BioSante may make, by news release or otherwise, from time to time. BioSante undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through news releases or through other public disclosure. By filing this report and furnishing this information, BioSante makes no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits*.

| Exhibit No. | Description |
|---|---|
| 99.1 | Information Regarding BioSante Which May Be Disclosed by BioSante Pharmaceuticals, Inc. in Presentations (furnished herewith) |
| 99.2 | Information Regarding BioSante and LibiGel® Which May Be Disclosed by BioSante Pharmaceuticals, Inc. in Presentations (furnished herewith) |



**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**BIOSANTE PHARMACEUTICALS, INC.**

By: /s/ Phillip B. Donenberg
Phillip B. Donenberg
*Senior Vice President of Finance, Chief Financial Officer and Secretary*

Dated: January 10, 2011



**BIOSANTE PHARMACEUTICALS, INC.**

**CURRENT REPORT ON FORM 8-K**

**EXHIBIT INDEX**

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**Exhibit 99.1**


Elestrin
estradiol gel 0.06%
FOR TOPICAL USE ONLY
Elestrin
estradiol gel 0.06%
BioSante
Pharmaceuticals
LibiGel

This presentation contains 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 presentation speak only as of the date of this presentation. BioSante undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.





# BioSante Investment Highlights

- **Specialty pharmaceutical company focused on developing products for female sexual health and oncology**
- **Products**
  - **Elestrin™: FDA approved product for hot flashes**
  - **LibiGel®: In Phase III for female sexual dysfunction, a potential blockbuster indication**
  - **Deep late stage product portfolio**
  - **Cancer immunotherapies**
- **People**
  - **Experienced management team**
  - **Proven ability to execute**
    - **Product development**
    - **FDA expertise**
    - **Licensing and M&A expertise**

# BioSante's Product Portfolio

| Product | Indication | Pre-Clinical | Early Human Clinical | Late Human Clinical | FDA approval/ Licensees |
|---|---|---|---|---|---|
| *Elestrin™ (estradiol gel)* | Menopausal symptoms | | | | *Azur Pharma* |
| *LibiGel® (testosterone gel)* | Female Sexual Dysfunction (FSD) | | | | *Non-partnered* |
| *Bio-T-Gel™ (testosterone gel)* | Male Hypogonadism | | | | *Teva* |
| *The Pill Plus™ (birth control with androgen)* | Contraception | | | | *Pantarhei for oral use Non-partnered for TD use* |
| *Cancer Immunotherapies (Vaccines)* | Various Cancers | | | | *Johns Hopkins* |

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# LibiGel® (testosterone gel for women)

***Indication:*** **Hypoactive Sexual Desire Disorder (HSDD) in menopausal women**

***Symptoms:*** **Lack of sexual desire and low sexual activity**

***Status:*** **Two Phase III efficacy trials ongoing**

- 500 women each
- Six months on therapy
- Both trials covered by an FDA SPA

**One cardiovascular safety study ongoing**

- Over 2,750 women randomized to date
- 2,700 women-years of exposure
- Cardiovascular and general safety shown
- Twelve months on therapy to submit NDA

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# LibiGel® Efficacy Trials & SPA

- **LibiGel efficacy trials**
  - Six month, randomized, double-blind, placebo-controlled trials
  - Co-primary endpoints: increase in total number of satisfying sexual events, and change in the mean desire
  - Secondary endpoint: decrease in distress associated with low desire
- **The SPA affirms that the LibiGel Phase III clinical plan is acceptable to support regulatory approval, including:**
  - Clinical trial design
  - Clinical endpoints
  - Sample size
  - Planned conduct
  - Statistical analyses
- **An FDA Advisory Committee on June 18, 2010 stated that HSDD is a significant medical condition for women**

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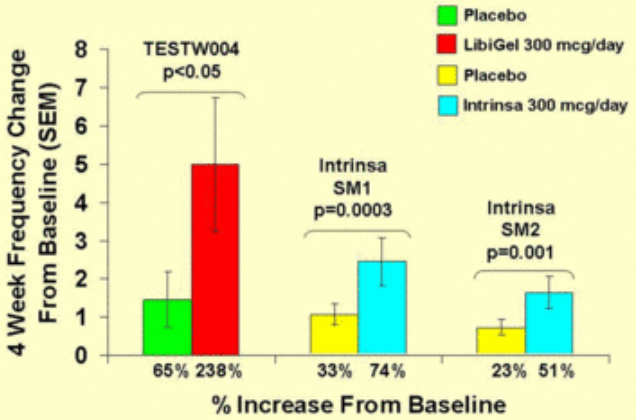
# Comparative Results of LibiGel® and Intrinsa




| Study Design | BioSante/ LibiGel® 3 month Phase II 300 mcg/day N=46 SM | P&G/ Intrinsa 6 month Phase III 300 mcg/day N=562 SM | P&G/ Intrinsa 6 month Phase III 300 mcg/day N=533 SM |
|---|---|---|---|
| % increase in sexual events 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

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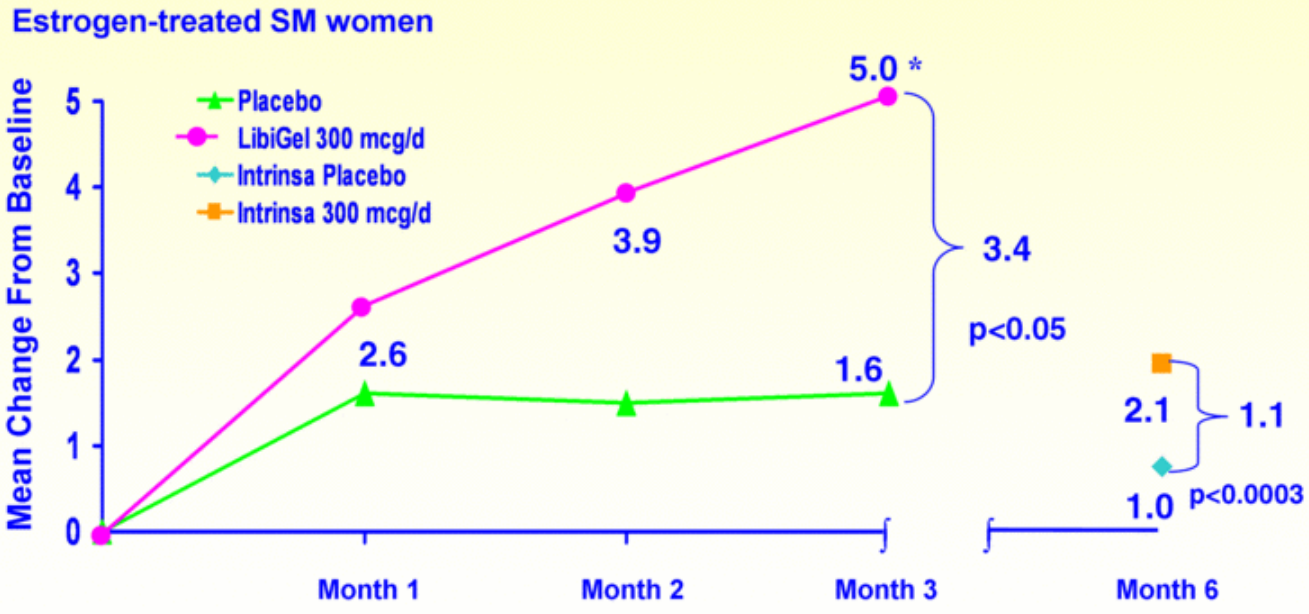
# LibiGel® vs. Intrinsa®

## Mean Change From Baseline in 4-Week Satisfying Sexual Event Rate




* p<0.0001 versus baseline

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# LibiGel Safety Study



- Primary safety outcome: the combined incidence of predefined CV events comprised of:
  - CV death
  - Nonfatal stroke
  - Nonfatal myocardial infarction
  - Hospitalized unstable angina
  - Coronary revascularization
  - Venous thromboembolic events (DVTs)
- Only 14 adjudicated CV events to date:
  a rate of approximately 0.52%; lower than 2% predicted
- Only eight (8) breast cancers reported to date:
  a rate of 0.30%; 0.35% predicted
- Independent DMC
  - four unblinded reviews conducted
  - study continues as per protocol, with no modifications
- Last review October 22, 2010; next review mid-Q1 2011

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# Potential Market for LibiGel®



- In 2009, over 4.0 million testosterone Rxs written off-label for treatment of Female Sexual Dysfunction (FSD)
  - Among surveyed physicians:
    - Greater than 80% indicate there is a need (or great need) for an FDA-approved therapy
    - 96% of patients will be switched from off-label use to LibiGel
    - The average GYN hears 37 FSD inquiries per month
- Market potential for FSD is more than $2.0 billion
- 43% of women (18-59) experience some degree of FSD (JAMA)
  - 31% experience low sexual desire specifically
  - 31% of men experience sexual dysfunction
- 43% of women (57-85) experience low desire (NEJM)
- LibiGel is patented until mid-2022

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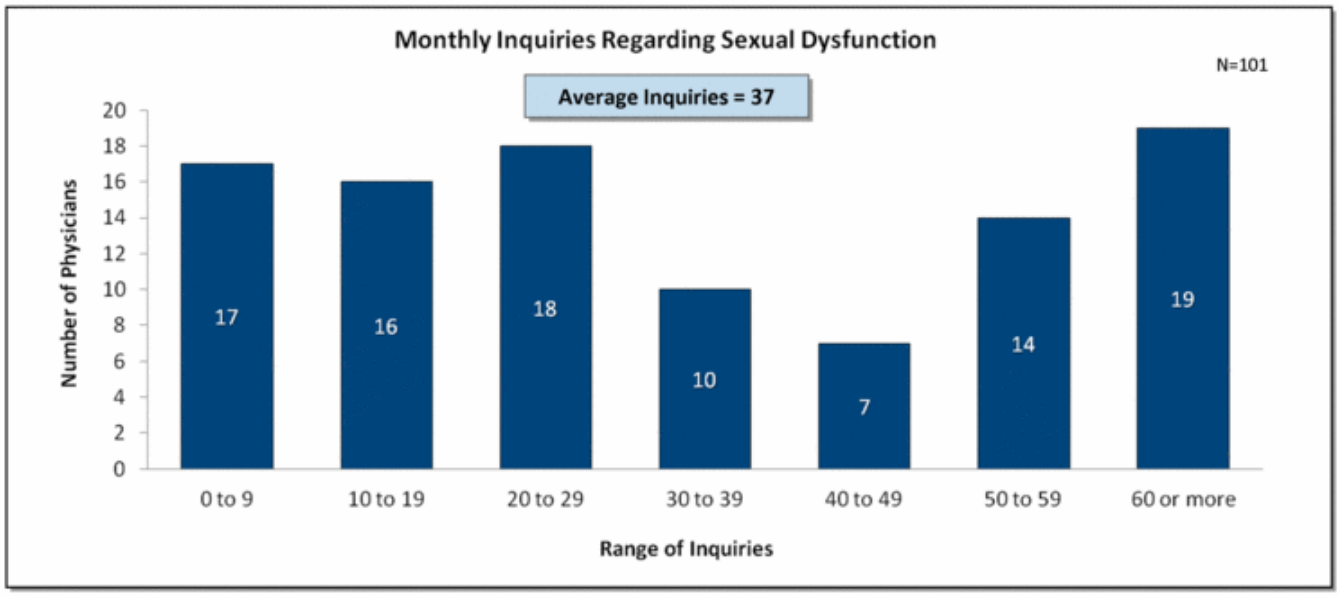
# Unmet Medical Need—Patient Inquiries

**Market research showed that sexual dysfunction is *one of the most common complaints* in gynecologist offices.**




***The frequency of inquiries related to female sexual dysfunction potentially could increase with a first-approved drug like LibiGel on the market.***

Source: Results of Campbell Alliance primary research surveys/interviews with 101 physicians. March 2010 to April 2010.





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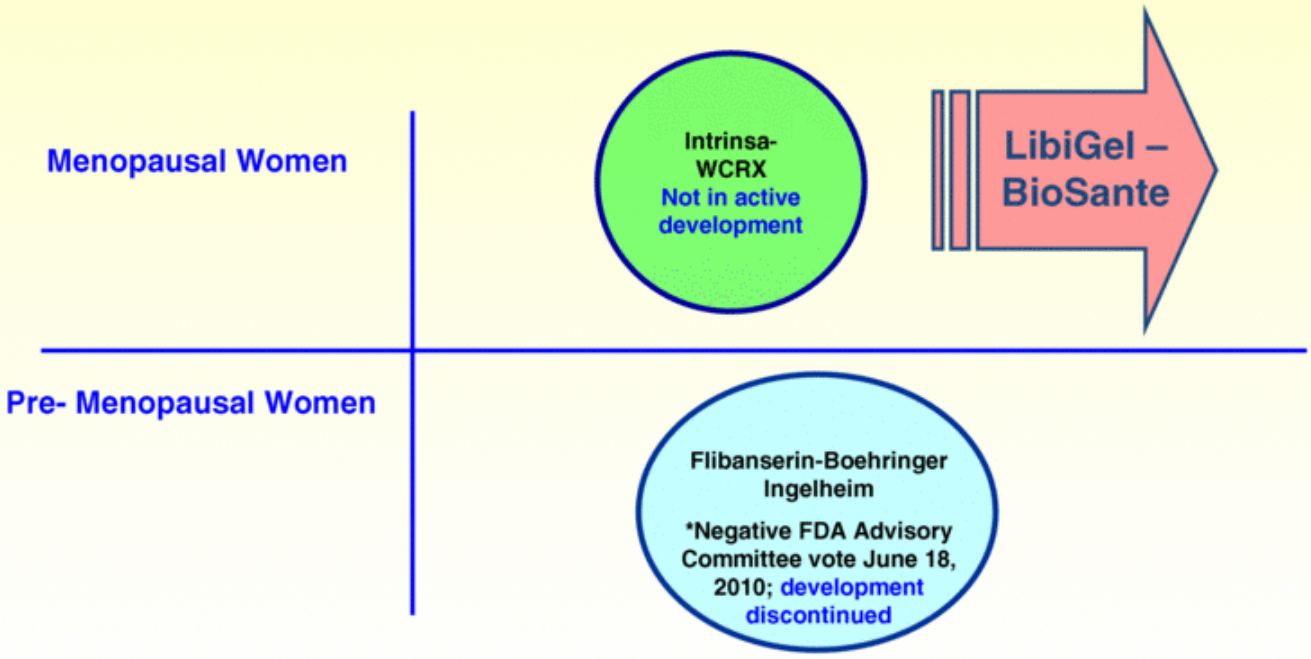
# HSDD Competitive Landscape

- **There is limited competition in the US HSDD market:** ***only LibiGel is in active late-stage development***




*ADIS, Companies' websites*

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# BioSante Cancer Vaccines

- **A portfolio of cancer vaccines in Phase II clinical trials, at minimal cost to BioSante**
  - Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
  - Dana-Farber Cancer Institute

- **Several cancer types are being studied:**
  - Leukemia
    - ✓ Chronic Myeloid Leukemia (CML)
    - ✓ Acute Myeloid Leukemia (AML)
  - Pancreatic cancer
  - Breast cancer
  - Multiple myeloma
  - Prostate (to begin in H1)

- **Four FDA Orphan Drug designations:**
  - Vaccine *to treat pancreatic cancer*
  - Vaccine *to treat acute myeloid leukemia*
  - *Vaccine to treat chronic myeloid leukemia*
  - *Vaccine to treat melanoma*

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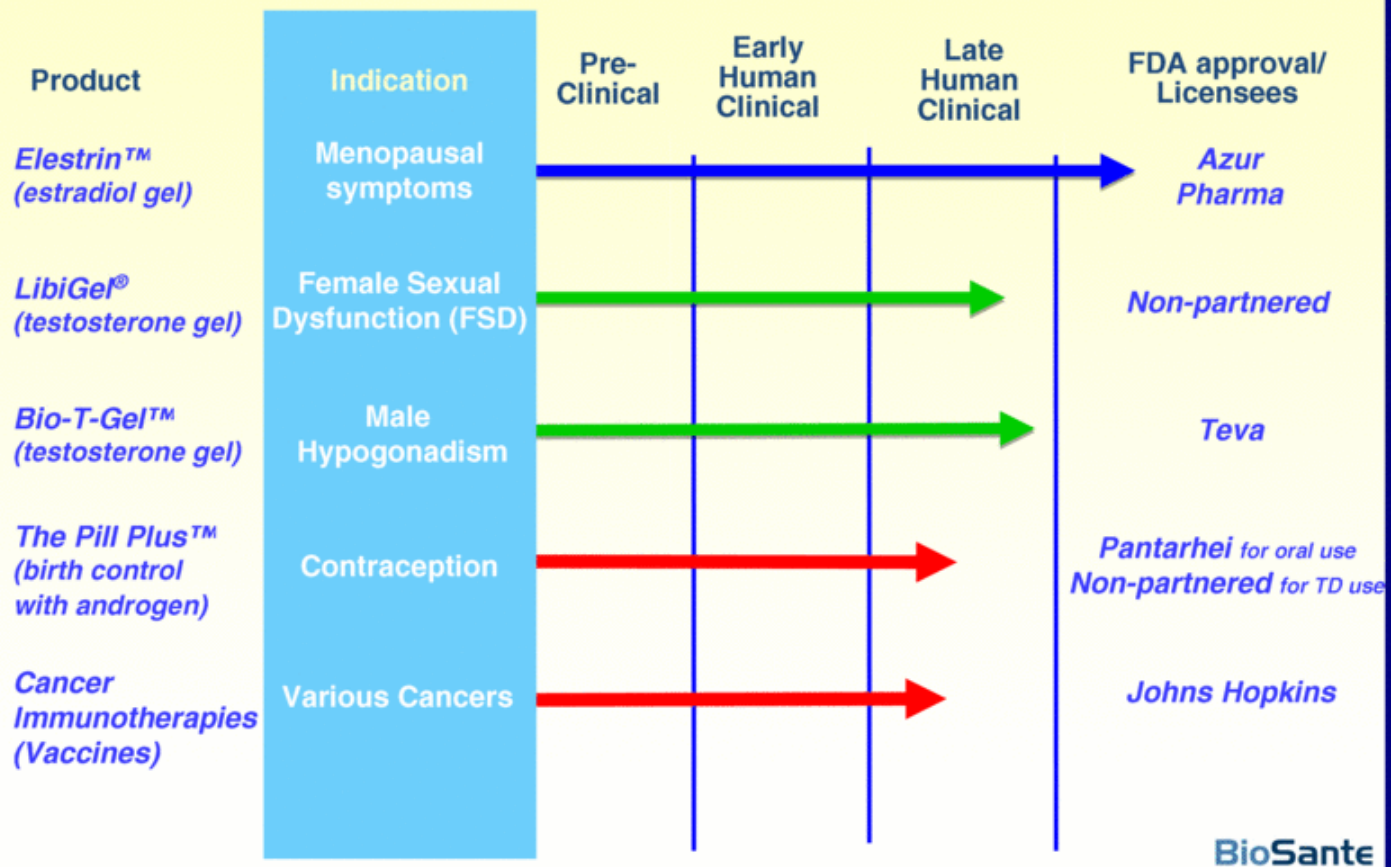
# BioSante's Product Portfolio








# BioSante Pharmaceuticals, Inc. Corporate Summary

# Capitalization and Cash
(January 4, 2011)

| | |
|---|---|
| • NASDAQ | BPAX |
| • Common stock outstanding | 81.4 million |
| • Warrants | 19.4 million |
| • Options | 5.7 million |
| • Fully diluted shares | 106.5 million |
| • Cash | Approx. $39 million |
| • Burn Rate | ~$3.5-$4.0 million/month |

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# Planned Milestones

- **LibiGel®**
  - Three Phase III studies — Ongoing
    - Independent DMC 5th safety review — Q1 2011
    - Submit NDA — 2011
    - Launch LibiGel — 2012
- **The Pill Plus™**
  - Report additional Phase II results - oral use — 2011
- **Bio-T-Gel™**
  - Submit to FDA for approval: Teva — Q1 2011
- **GVAX Cancer Vaccines** — Ongoing
  - Multiple Phase II trials
  - Four orphan drug designations

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# BioSante and LibiGel® Market Overview

January 2011

## Disclaimer—Forward-looking Statements

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BioSante Pharmaceuticals

# BioSante Overview

## Company Information




BioSante Pharmaceuticals

## Corporate Background

**BioSante is a specialty pharmaceutical company focused on developing and commercializing products for female sexual health and oncology.**

| | |
|---|---|
| **Business Overview** | BioSante is focused on the ***development and commercialization*** of products for female sexual health, menopause, contraception, male hypogonadism, and oncology. |
| **Clinical Portfolio** | BioSante currently has ***promising late-stage assets*** for the treatment of female sexual dysfunction, contraception, and male hypogonadism, as well as a portfolio of cancer vaccines. |
| **Management Team** | BioSante has a strong management team with ***extensive product development*** and public company experience. |




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## BioSante's Product Portfolio

**BioSante has several late-stage assets indicated for female and male sexual health, as well as a portfolio of cancer vaccines.**

| Product | Indication | Preclinical / Early Human Clinical / Late Human Clinical / FDA Approval | Marketing Rights |
|---|---|---|---|
| ***Elestrin™*** (Estradiol gel) | Menopausal symptoms | Marketed | Azur Pharma (US rights); BioSante Pharmaceuticals (China, and various other countries) |
| ***LibiGel®*** (Testosterone gel) | Hypoactive Sexual Desire Disorder (HSDD) | Phase III under an SPA | BioSante Pharmaceuticals (US, China, and various other countries) |
| ***The Pill-Plus™*** | Contraception + Androgen | Phase II | Pantarhei Bioscience (US, Oral use); BioSante Pharmaceuticals (US, TD use) |
| ***Bio-T-Gel™*** | Male Hypogonadism | FDA submission < 6 months | Teva (US); BioSante Pharmaceuticals (Ex-US) |
| **Cancer Vaccines** | Various Cancers | Phase II | BioSante Pharmaceuticals (Global) |




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# LibiGel® Overview




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# LibiGel Opportunity—Overview

**LibiGel, a valuable asset with a well-defined regulatory pathway, is anticipated to launch in 2012.**

**Asset Summary**

1. **High Unmet Need**
   No FDA-approved agents exist for female sexual dysfunction (FSD). Current off-label prescribing is estimated at 4.1M prescriptions per year.
2. **Differentiated Asset With Favorable Profile**
   Phase II results showed remarkable (238%) improvement in satisfying sexual events and a safety profile similar to placebo. Additionally, blinded ongoing results show lower rates of serious CV events than expected.
3. **First to Market**
   LibiGel is anticipated to be the first product FDA-approved in the US for the treatment of FSD or related conditions.
4. **Favorable Response From Prescribers**
   Interviewed physicians were very bullish on LibiGel. They were receptive to the product profile and suggested that this would replace almost all of the current off-label prescribing for FSD.
5. **Large Market Potential**
   LibiGel is anticipated to launch in 2012 —with potential to be a blockbuster asset.




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# High Unmet Need—Large Patient Population

**Female sexual dysfunction includes a range of conditions that include hypoactive sexual desire disorder (HSDD).**

**Female Sexual Dysfunction**

**Sexual Desire Disorders**

- Hypoactive Sexual Desire Disorder: Absence or deficiency of sexual interest or desire
- Sexual Aversion Disorder: Avoidance of genital contact with a sexual partner

**Sexual Arousal Disorder**

- Female Sexual Arousal Disorder: Inability to attain or maintain an adequate lubrication-swelling response

**Orgasmic Disorder**

- Female orgasmic disorder: Delay in or absence of orgasm after a normal sexual excitement phase

**Sexual Pain Disorder**

- Dyspareunia: Genital pain associated with sexual intercourse
- Vaginismus: Involuntary contraction of the perineal muscles

***Approximately 40 million women in the US suffer from Female Sexual Dysfunction.***

Sources: Elder J and Braver Y. Female Sexual Dysfunction. Cleveland Clinic. Available at http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/womens-health/female-sexual-dysfunction/. Accessed February 2010; Diagnostic and Statistical Manual of Mental Disorders 4th edition, text revision; West S et al. Prevalence of low sexual desire and hypoactive sexual desire disorder in a nationally representative sample of US women. *Arch Internal Medicine*. July 14, 2008; Volume 168; MayoClinic.com. Low Sex Drive in Women. Available at: http://www.mayoclinic.com/health/low-sex-drive-in-women/DS01043. Accessed June 2010; Laumann EO, Paik A, Rosen RC. Sexual Dysfunction in the United States. *JAMA*. 1999 Feb 10;281(6):537-44.




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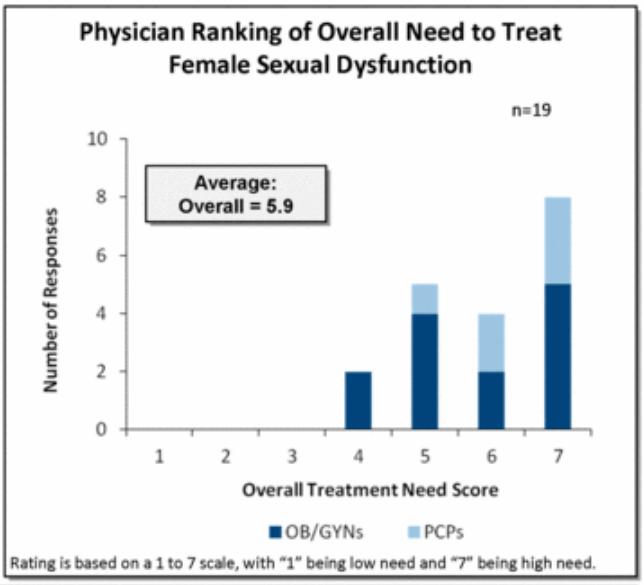
## High Unmet Need—Desire for Pharmaceutical Treatment Options

**Physicians are looking for pharmaceutical treatment options for FSD even though no therapeutic options currently exist.**

- Physicians responded that overall ***awareness of FSD is increasing*** due to
  - Approved products for male sexual dysfunction
  - Less cultural stigma
  - Aging US patient population
- Overall, the physician panel indicated a ***high unmet medical need***, with an even higher perceived medical need in the primary care community.

***"The need to treat is very high because it's a very important aspect of a patient's life." – Physician***



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

***The majority of physicians interviewed believed that female sexual dysfunction is an important and legitimate disorder <u>requiring treatment</u>.***

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.

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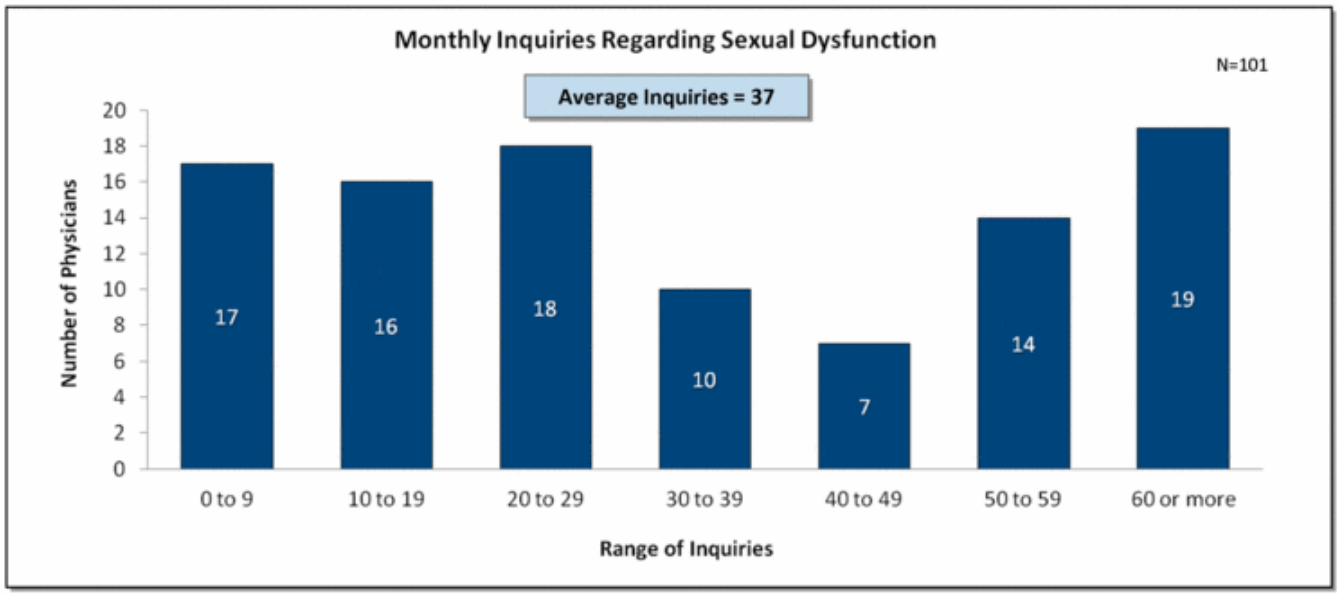
## High Unmet Need—Patient Inquiries

**Market research showed that sexual dysfunction is *one of the most common complaints* in gynecologist offices.**




***The frequency of inquiries related to female sexual dysfunction potentially could increase with a first-approved drug like LibiGel on the market.***

Source: Results of Campbell Alliance primary research surveys/interviews with 101 physicians. March 2010 to April 2010.

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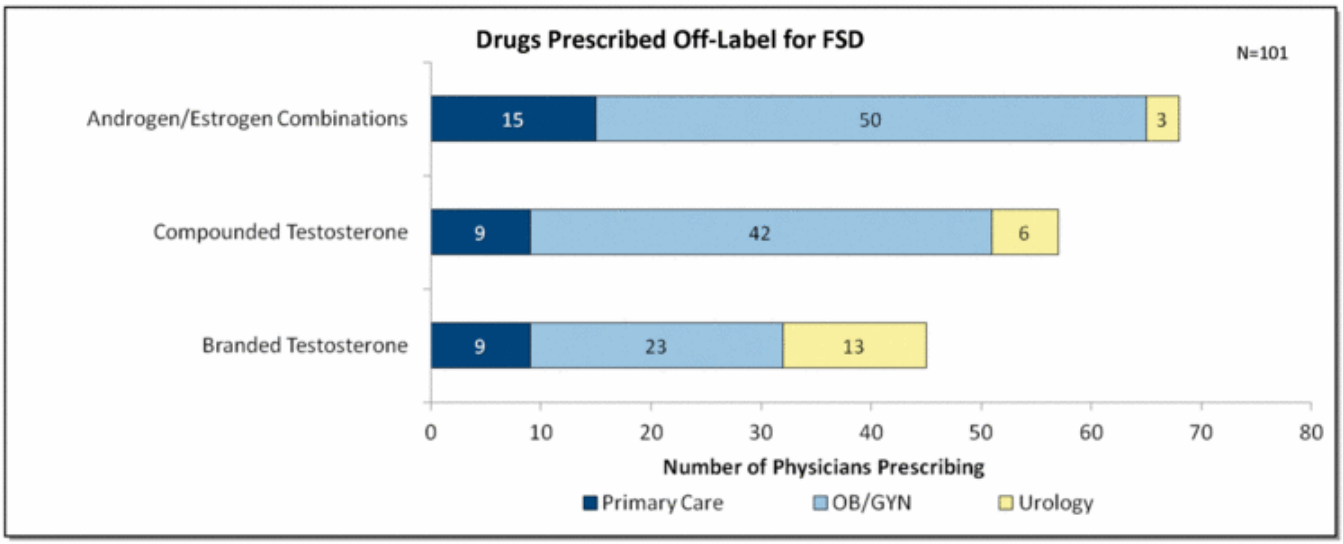
# High Unmet Need—Current Hormone Replacement Therapies

**Although there are currently no medications approved by the FDA for female sexual dysfunction, the significant *majority of physicians reported prescribing androgen and androgen-estrogen combinations off-label* for their FSD patients.**




***A significant majority of physicians are prescribing androgen, and androgen-estrogen product combinations despite the lack of approved products within this space.***

Source: Results of Campbell Alliance primary research surveys/interviews with 101 physicians. March 2010 to April 2010.

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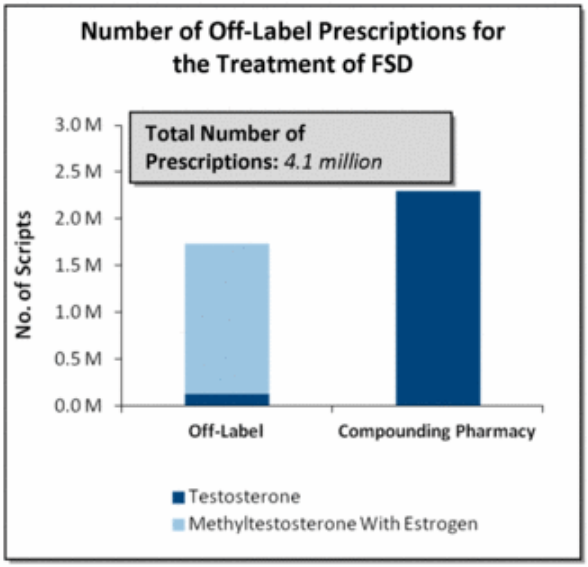
# High Unmet Need—Prescription Rates for FSD Therapies

**Testosterone therapies are prescribed off-label to alleviate the symptoms of FSD, but among these marketed products, there is a lack of clinical studies and consistent, precise dosing in women with FSD.**

| Drug Product | Sample Products | Benefits | Limitations/ Side Effects |
|---|---|---|---|
| Testosterone | ▪ Androgel<br>▪ Testim | Potentially increases sexual desire by raising levels of testosterone | ▪ No data indicating appropriate dose (poor dosing control) |
| Methyl Testosterone With Estrogen | ▪ Estratest<br>▪ EEMT<br>▪ Essian H.S. | | ▪ Limited efficacy data available<br>▪ Potential androgenic side effects<br>▪ Potential liver toxicity |




***Among available testosterone products, approximately 1.8 million prescriptions are filled off-label annually for FSD. Additionally, research indicates 2.3 million prescriptions for testosterone are filled at compounding pharmacies.***

Sources: Elder J, Braver Y. Female Sexual Dysfunction. Cleveland Clinic. Available at http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/womens-health/female-sexual-dysfunction/. Accessed February 2010; IMS HEALTH Confidential and Proprietary; Source: IMS Health Incorporated, National Sales Perspectives; Results of Campbell Alliance primary research surveys/interviews with 101 physicians. March 2010 to April 2010.

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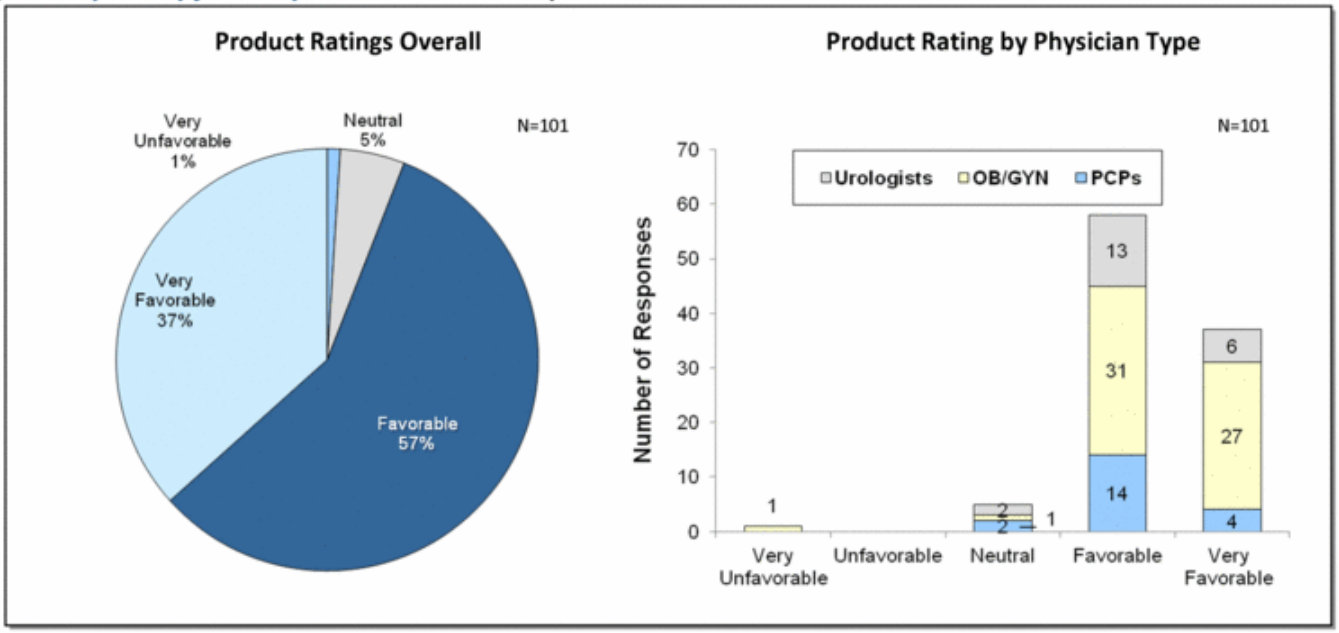
# Quantitative Market Research—Physician Reaction to LibiGel

**Additionally, quantitative market research was conducted with 101 physicians. *94% of physicians were either favorably or very favorably inclined* towards the profile of LibiGel.**




***Physicians' favorable reaction can be viewed as a predictor of their willingness to prescribe based on clinical profile alone (without consideration of external factors).***

Source: Results of Campbell Alliance primary research surveys/interviews with 101 physicians conducted in March 2010 to April 2010.

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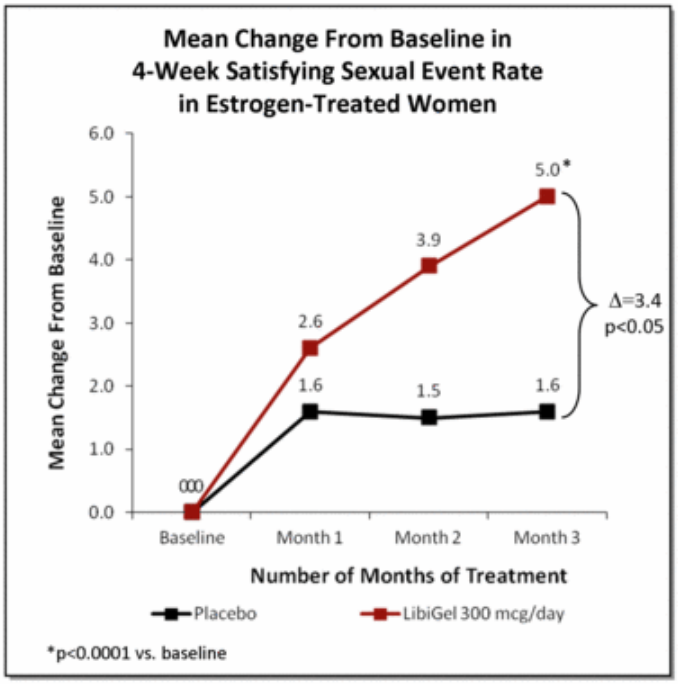
## Differentiated Asset With Favorable Profile

**LibiGel has shown to be an effective and safe agent for the treatment of HSDD.**

- There is currently ***no clinically tested, FDA-approved pharmaceutical product for the treatment of FSD***, and LibiGel has the potential to become the ***first-to-market product*** for treating hypoactive sexual desire disorder (HSDD) in menopausal women.
- LibiGel successfully completed a phase II clinical trial showing ***a 238% increase in the number of satisfying sexual events*** vs. baseline (p<0.0001) and statistically significantly better than placebo (p<0.05) with ***a safety profile similar to placebo***.
- Replicate phase III safety and efficacy trials currently are ***recruiting under an SPA.***
- ***Positive blinded ongoing results*** (featuring lower than expected CV rates) have been demonstrated in a blinded phase III ***long-term cardiovascular safety study***.




Source: Clinical studies sponsored by BioSante.

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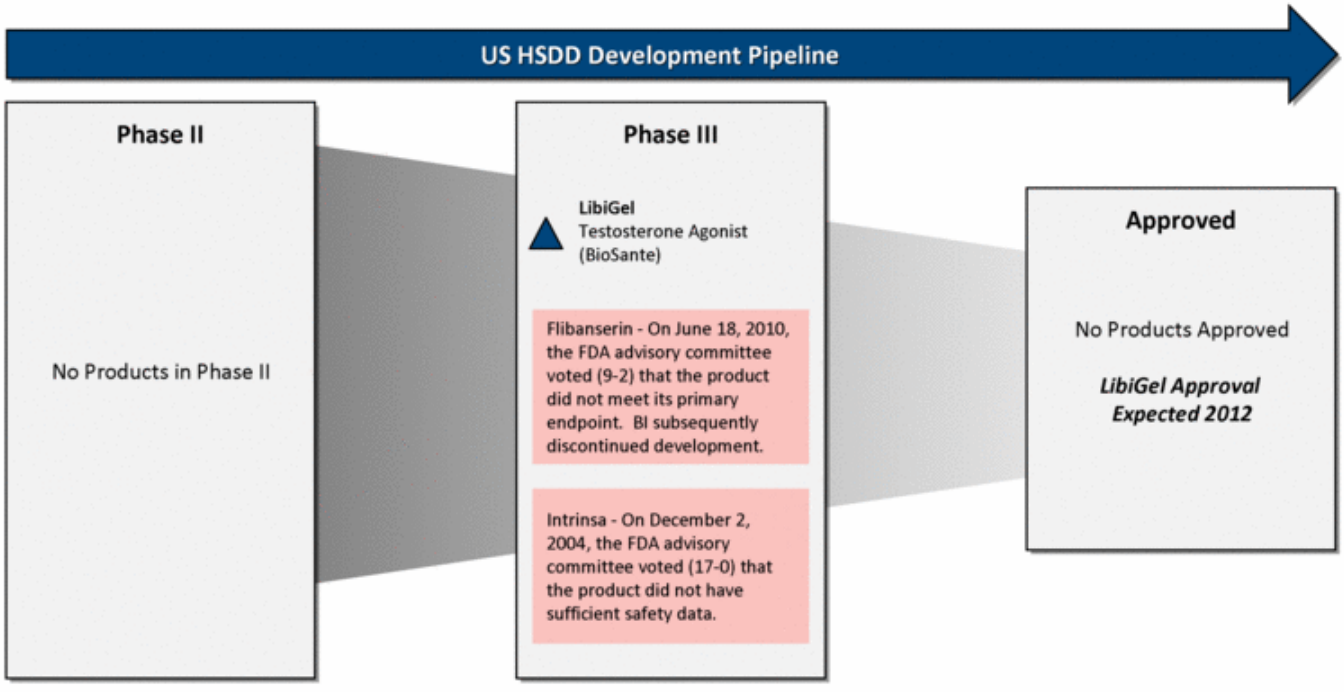
## Anticipated to Be First to Market

**LibiGel is anticipated to be first-to-market product for the treatment of HSDD in the US.**




Sources: Adis R&D Insight; PharmaProjects. Accessed June 2010.

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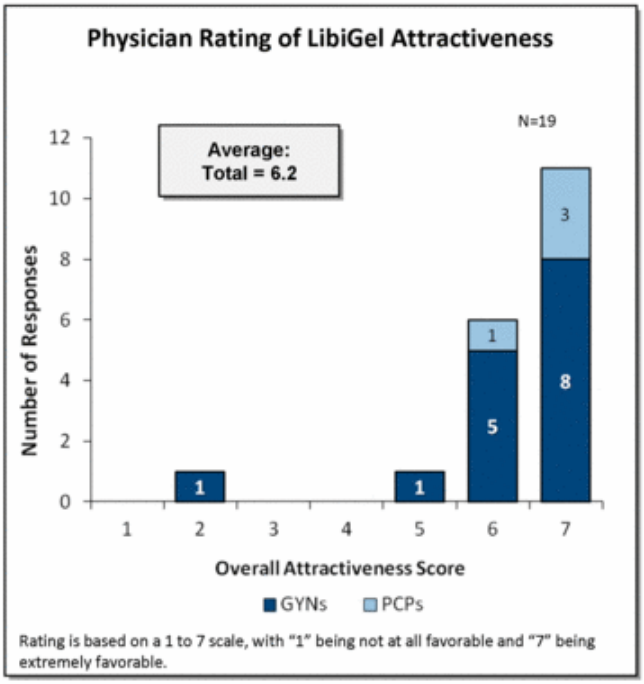
# Favorable Response From Prescribers

**Almost all interviewed physicians rated LibiGel highly with the majority of physicians rating it a score of 7 out of 7.**




Rating is based on a 1 to 7 scale, with "1" being not at all favorable and "7" being extremely favorable.

- All but one interviewed physician rated LibiGel a ***5 or higher.***
- Physicians noted several positive attributes of LibiGel:
  - Topical Mode of Administration
  - Efficacy
  - Female-Specific Dosing
  - Quick Absorption
  - Lack of Side Effects

> *"This is answering **just what we need**, especially with the low side effects."*
>
> – Gynecologist

> *"This is **what we've been waiting for**, a female dosing version of testosterone in a topical form… especially with some studies and pharmaceutical grade **consistency**."*
>
> – Gynecologist

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.

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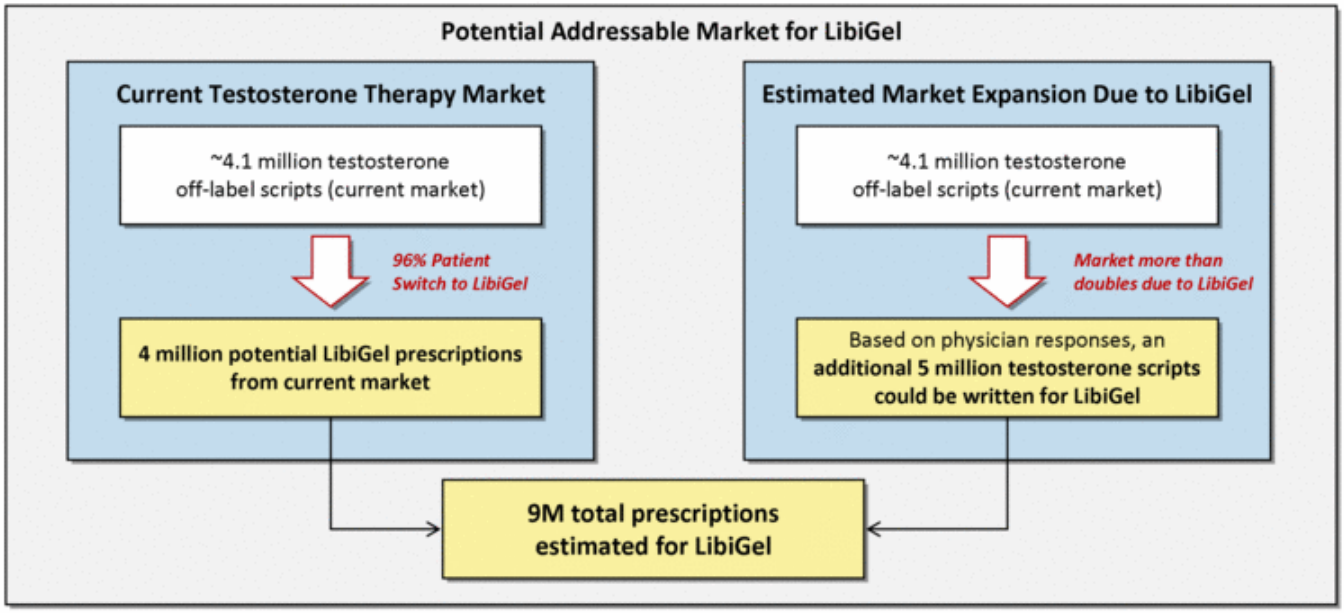
## Revenue Opportunity—US Revenue Estimates for LibiGel

**Due to favorable efficacy, safety, route of administration and FDA approval, LibiGel is *anticipated to dominate the current testosterone market* and *grow the FSD-treated population*—achieving blockbuster status.**




***Surveyed physicians report that 96% of current testosterone patients will be switched to LibiGel; the market is expected to double once a product is FDA approved***

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## LibiGel Clinical Development Status

**Current phase III studies in progress for LibiGel include replicate efficacy and safety trials as well as a long-term cardiovascular safety study.**

### Phase III Replicate Efficacy and Safety Trials

- Two phase III trials already are underway *as specified by FDA's Special Protocol Assessment (SPA).*
- Trials are designed to establish the efficacy and safety of LibiGel (testosterone gel) in the treatment of oophorectomized postmenopausal women with Hypoactive Sexual Desire Disorder (HSDD).
- The 24-week, randomized, double-blind, placebo-controlled trials include 500 subjects each, 250 per treatment group.
- LibiGel treatment group receives 300mcg/day dosing.

### Phase III Safety Study

- A phase III randomized, double-blind, placebo-controlled multicenter cardiovascular safety study is well underway, *developed in consultation with and agreement from the FDA.*
- To date, over 2,750 postmenopausal women with elevated CV risk have been enrolled.
- CV event and rates have been very low to date in subjects who are at the higher end of the CV risk continuum for the intended treatment population. These blinded data demonstrate a lower-than-expected rate of serious CV events in the study thus far.
- NDA submission is planned after an average of 12 months of exposure.
- Subjects will be followed for four years after the initial 12 months post-NDA submission, potential approval, and launch.

***Upon successful completion of the 24-week replicate efficacy trials and 12 months average exposure in a phase III CV safety study, an NDA for LibiGel will be submitted, and a product launch is anticipated in 2012.***




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