



# BioSante Pharmaceuticals



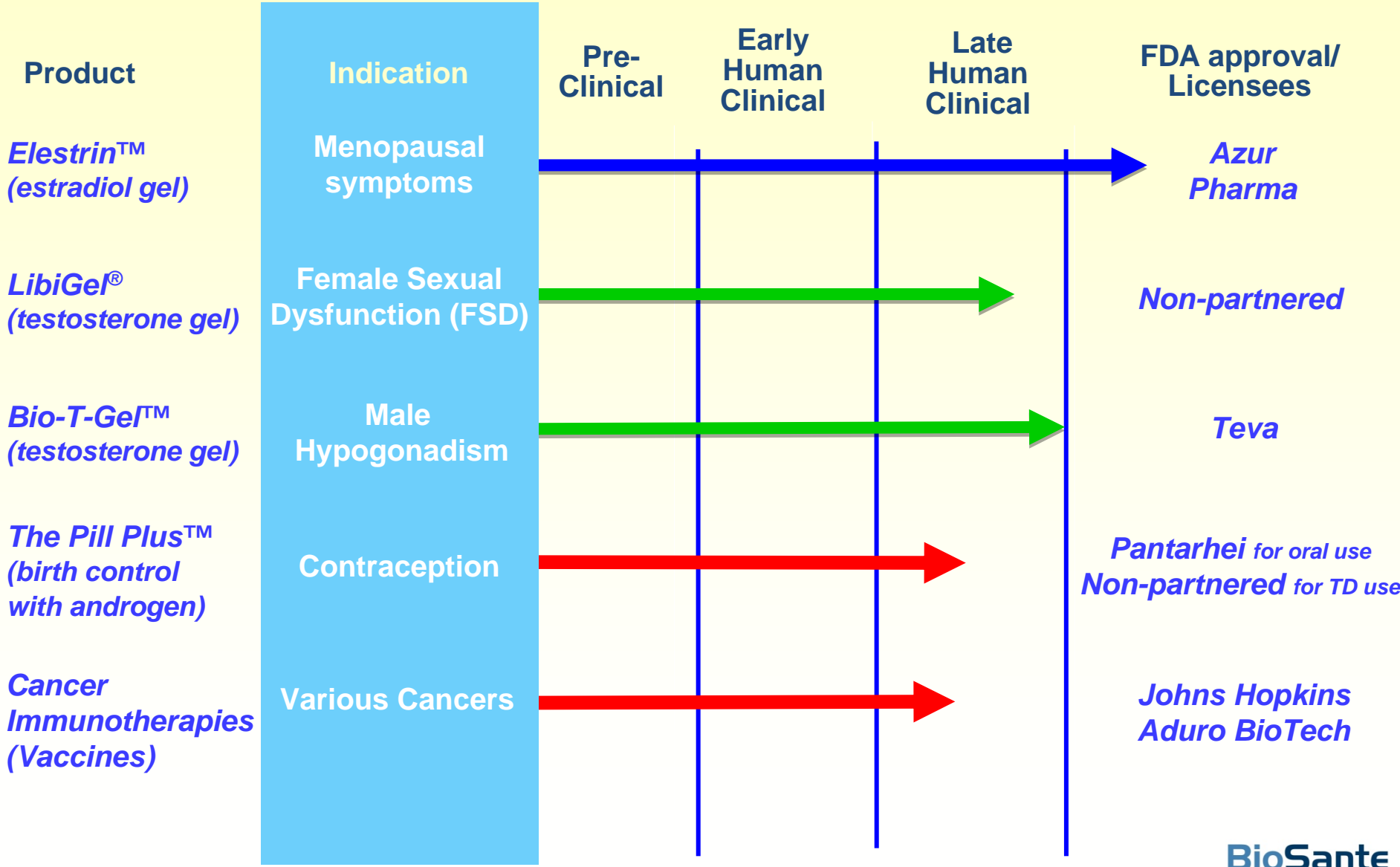
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# BioSante Investment Highlights

- **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**
  - **Bio-T-Gel™: NDA filed by Teva**
  - **Cancer immunotherapies**
- **People**
  - **Experienced management team**
  - **Proven ability to execute**
    - **Product development**
    - **FDA expertise**
    - **Licensing and M&A expertise**



# BioSante's Product Portfolio



# Bio-T-Gel™ (testosterone gel for men)

- **Indication: Male hypogonadism**
  - **Testosterone gel sales in 2010: \$1.1 billion**
- **Bio-T-Gel was developed initially by BioSante**
  - **then licensed to Teva**
- **Teva is responsible for legal, regulatory and marketing activities**
- **Bio-T-Gel NDA submitted in January 2011**
  - **accepted for filing by FDA in March 2011**
  - **Abbott files patent infringement claim against Teva**
  - **Teva NDA asserts no patent infringement**
- **PDUFA date is November 14, 2011**

# LibiGel<sup>®</sup> (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

- Enrollment completed in both trials
- Over 500 women each
- Six months on therapy
- Both trials covered by an FDA SPA

**One cardiovascular safety study ongoing**

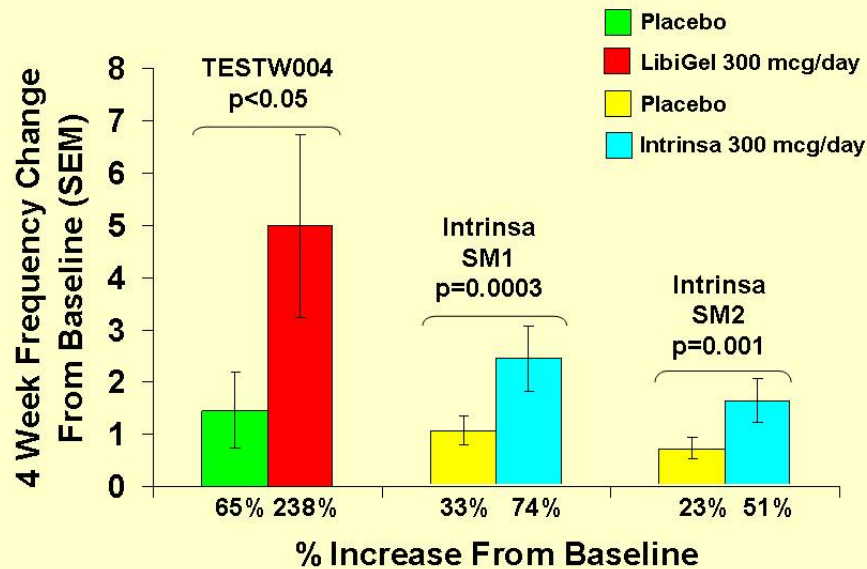
- Enrollment completed: 3,656 women randomized
  - Over 4,000 women-years of exposure, to date
- Unblinded sample size analysis (May 2011) by independent statistician indicated:
  - a minimum 90% probability of success of the safety study to show the safety of LibiGel at the primary data analysis
- BioSante remains blinded to all data



# LibiGel<sup>®</sup> 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**

# Comparative Results of LibiGel<sup>®</sup> and Intrinsa



**BioSante/  
LibiGel<sup>®</sup>**

**P&G/  
Intrinsa**

**P&G/  
Intrinsa**

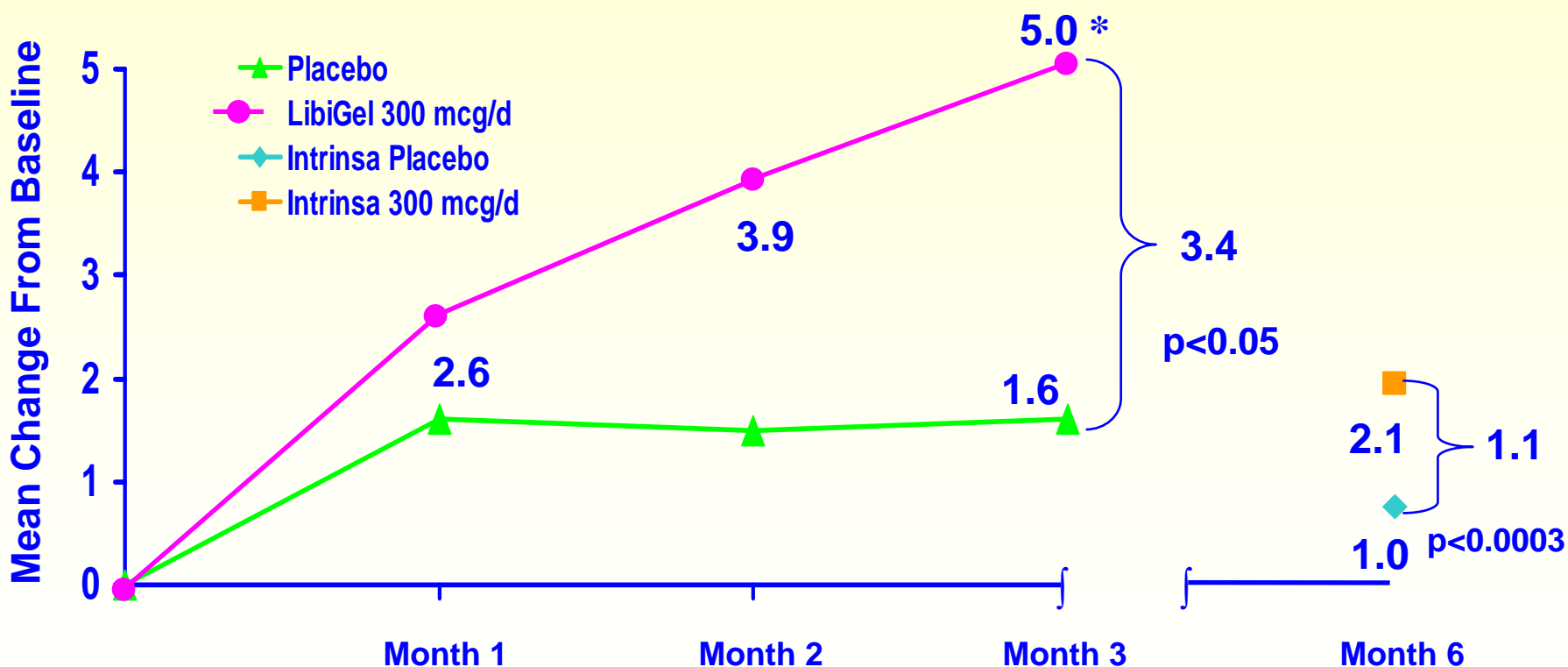
Study Design	3 month Phase II 300 mcg/day N=46 SM	6 month Phase III 300 mcg/day N=562 SM	6 month Phase III 300 mcg/day N=533 SM
% increase in sexual events from baseline	238%*	74%*	51%*
# increase active v. placebo	5.0 v. 1.6*	2.13 v. 0.98*	1.56 v. 0.73*
Application site reactions	rare	~ 30%	~ 30%

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

# LibiGel<sup>®</sup> vs. Intrinsa<sup>®</sup>

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

Estrogen-treated SM women



\* p < 0.0001 versus baseline

# LibiGel Safety Study

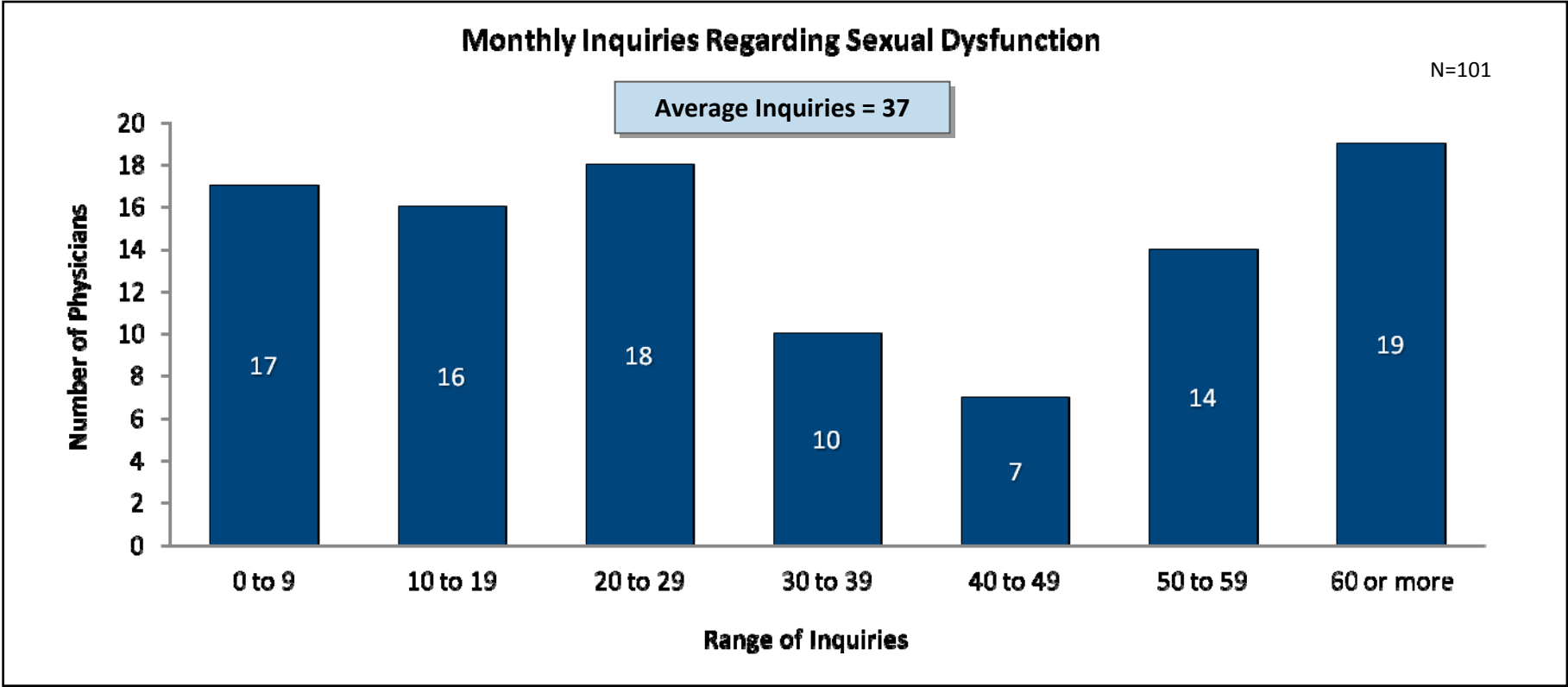
- **Primary safety outcome: the combined incidence of predefined CV events comprised of:**
  - CV death
  - Nonfatal stroke
  - Nonfatal myocardial infarction
  - Hospitalized unstable angina
  - Coronary revascularization
  - Venous thromboembolic events (DVTs)
- **Only 22 adjudicated CV events to date: a rate of approximately 0.58%; lower than anticipated**
- **Only nine (9) breast cancers reported to date: a rate of 0.24%**
- **The sample size analysis required us to stop enrollment when there is at least a 90% chance of showing the CV safety of LibiGel compared to placebo 12 months after last subject enrolled**
  - **Criterion met; enrollment complete at 3,656 subjects**
- **Independent DMC**
  - six unblinded reviews conducted
  - study continues as per protocol, with no modifications

# Potential Market for LibiGel®

- In 2010, approximately 4.0 million testosterone Rx's 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
- 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

# Unmet Medical Need—Patient Inquiries

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

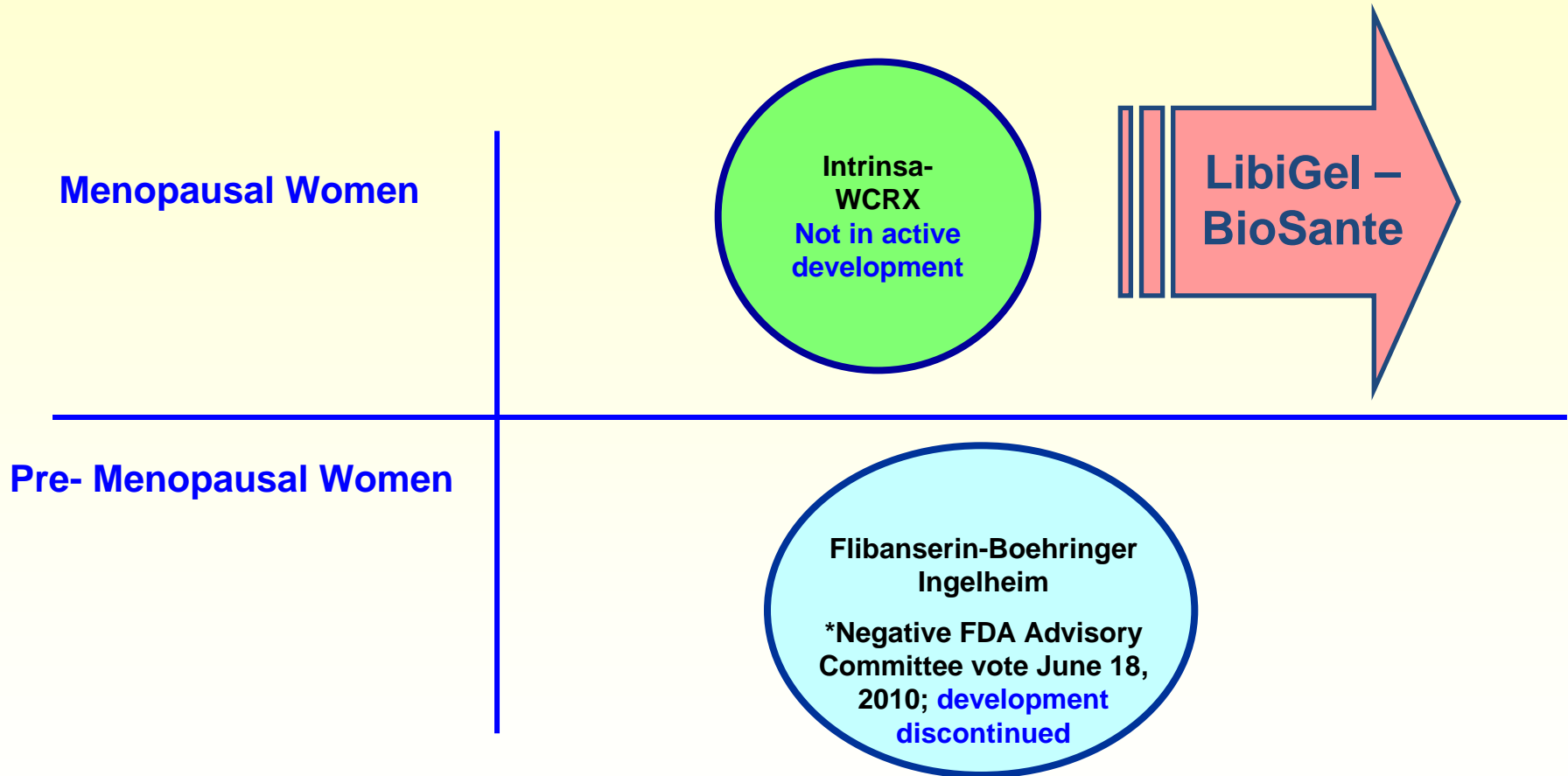


*The frequency of inquiries related to female sexual dysfunction potentially could increase with a first-approved drug like LibiGel on the market.*

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

# HSDD Competitive Landscape

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



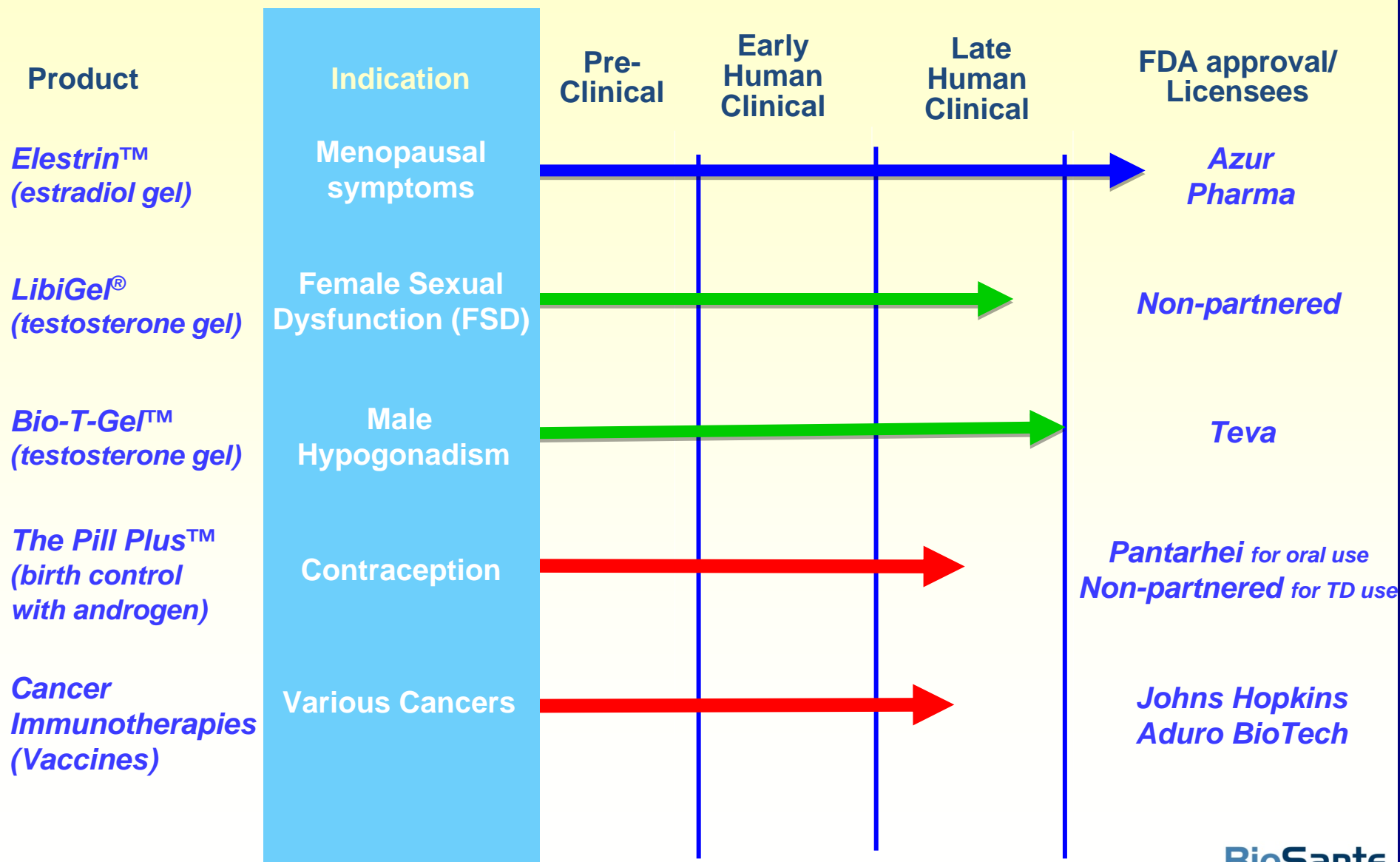
ADIS, Companies' websites

# 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)
  - Breast cancer
  - Multiple myeloma
  - Pancreatic cancer (two trials to being in 2011)
  - Melanoma (to begin in 2011)
  - Prostate (to begin in 2011)
- 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*



# BioSante's Product Portfolio



# **BioSante Pharmaceuticals, Inc. Corporate Summary**

# Capitalization and Cash

(March 31, 2011)

- 
- **NASDAQ**
  - **Common stock outstanding** 93.6 million
  - **Warrants** 24.0 million
  - **Options** 5.3 million
  - **Fully diluted shares** 122.9 million
- BPAX**
- **Cash** Approx. \$51.0 million
  - **2011 Average Burn Rate** \$4.0 million/month
  - **2012 Average Burn Rate** \$3.0 million/month

# Planned Milestones

- **LibiGel®**
  - **Three Phase III studies** **Ongoing**
    - ✓ Enrollment in efficacy trials completed Q1 2011
    - ✓ Independent DMC 6th safety review Q2 2011
    - ✓ Complete enrollment in safety study Q2 2011
  - ❖ **Top-line efficacy data** Q4 2011
  - ❖ **Top-line safety data** Q3 2012
  - ❖ **Submit NDA** 2012
  
- **Bio-T-Gel™**
  - **NDA filed** Q1 2011
  - **PDUFA date** November 14, 2011
  
- **The Pill Plus™**
  - **Report additional Phase II results - oral use** 2011
  
- **BioSante Cancer Vaccines**
  - **Multiple Phase II trials** **Ongoing**



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