

With An Eye on Women's Sexual Health, BioSante Pharmaceuticals, Inc. is Developing their LibiGel® for the Treatment of Female Sexual Dysfunction for which there is No Approved Product in the United States

**Healthcare
Biotechnology
(BPAX-NASDAQ)**

BioSante Biopharmaceuticals, Inc.

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**Stephen M. Simes
Vice Chairman, President and CEO**

BIO:

Mr. Simes has served as Vice Chairman, President and Chief Executive Officer, and a director of BioSante Pharmaceuticals, Inc. since 1998. From 1994 to 1997, Mr. Simes was President, Chief Executive Officer and a Director of Unimed Pharmaceuticals, Inc., (currently a wholly owned subsidiary of Abbott Laboratories) a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993,

Gynex was acquired by Savient Pharmaceuticals Inc. (formerly Bio-Technology General Corp.), and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Savient Pharmaceuticals Inc. Mr. Simes's career in the pharmaceutical industry started in 1974 with G.D. Searle & Co. (now a part of Pfizer Inc.).

Company Profile:

BioSante Pharmaceuticals, Inc. 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. 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 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.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com**

CEOCFO: Mr. Simes, what was your vision when you founded BioSante?

Mr. Simes: BioSante is a product development company. From the beginning, we have had our eye on

women's sexual health. Right now, we are developing a product, LibiGel®, for the treatment of female sexual dysfunction for which there is no product approved in the United States. We believe this represents a blockbuster opportunity.

CEOCFO: What are some of the current products from BioSante?

Mr. Simes: We have our first FDA approved product, which was approved several years ago, our Elestrin™, which is an estrogen gel for the treatment of hot flashes in menopausal women. The hot flash market in the US today is about \$1.5 to \$2.0 billion market, and we are participating in that market. We have had the good fortune of taking a product from a formulation on a piece of paper through clinical development all the way through to a non-conditional FDA approval. The driver for BioSante in the near-term is our LibiGel, which is for a very exciting indication and a true unmet medical need in women.

CEOCFO: How does LibiGel work?

Mr. Simes: LibiGel is a testosterone gel. As we age, both men's and women's testosterone levels decline. Although it is not well known, a normal pre-menopausal woman actually has more testosterone flowing in her blood than she has estrogen. As women get older, their testosterone levels go down, and with the declining testosterone levels often their sexual desire and sexual activity decline. What LibiGel aims to do is bring those testosterone levels back to where they used to be and to restore sexual desire and sexual activity.

CEO CFO: What about potential side-effects?

Mr. Simes: The traditional side-effects that people worry about with testosterone in women are acne or hirsutism, which is hair growth where you don't want it. However, with LibiGel we are returning levels to their previous normal levels and in our clinical studies and in other published work there is no difference in those types of androgenic effects between active and placebo, so that this is not a significant issue for most women. The other issue is cardiovascular disease and breast cancer concern, and we now are conducting a LibiGel Phase III clinical safety study in which we are tracking cardiovascular events and breast cancer. I am happy to report we now are beginning our fourth year of this study, and we have over 3,000-women-years of experience in about 3,000 women. We have had a very low event rate of cardiovascular disease and of breast cancer, so we are showing quite definitively the safety of testosterone in women.

CEO CFO: Has testosterone been tried before; in what way is LibiGel different?

Mr. Simes: As I mentioned there is no product FDA-approved for the treatment of female sexual dysfunction, specifically hypoactive sexual desire disorder, so nobody has been successful at providing to the FDA the safety and efficacy data required to get approval for a product. There are two issues of critical importance: one is the efficacy of a product, and the FDA end-points are an increase in sexual desire and an increase in the number of satisfying sexual events. We are measuring those using validated instruments in two LibiGel Phase III efficacy trials. The other critical issue is the safety of a product. We have known for many years that testosterone can increase desire and sexual activity; what has not been produced yet are the safety data that will convince the FDA that it is safe to use testosterone in women. We are working to provide these data by conducting the very large LibiGel Phase III safety study now in its fourth year. We are planning to submit our

new drug application requesting approval in 2012.

CEO CFO: Has the FDA published guidance on how you should get reports on the results of your drugs?

Mr. Simes: Yes, the FDA has been very clear in how to conduct clinical studies and how to collect data through diaries and questionnaires in clinical studies that measure "patient reported outcomes." In fact, the FDA published Guidances on PROs in 2006 and 2009.

CEO CFO: What is different about your approach; is it in the delivery?

Mr. Simes: We have figured out how to deliver testosterone. Testosterone cannot be delivered by mouth because it gets broken down in the liver. Therefore, it has to be delivered transdermally, or through the skin. The two leading ways would be by a

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patch or a gel, and our technology is gel technology. In addition, we have identified the lowest effective dose to increase the number of satisfying sexual events. We are the first and only company who has agreed to conduct the very large safety study required by the FDA. Because in this new environment, especially post VI-OXX coming off the market because of cardiovascular events and risk, the FDA is requiring a much higher hurdle for proving the safety of a product. Therefore, we have embarked on this large LibiGel Phase III safety study and we now are showing in our study the safety of testosterone, and specifically LibiGel, in women.

CEO CFO: Are you engaged in partnerships or joint ventures or is it strictly BioSante?

Mr. Simes: We are a public company as you know, and we have raised enough money to implement our plans. We do not have a partner for

LibiGel. Our strategy has been to develop LibiGel as long as we can support the work, because we believe that from a stockholder point of view the value of the product increases as we take the product through later and later stages of development. Therefore, we contract directly with clinical investigators in the U.S. and Canada. We have about 150 different clinical sites conducting the studies, and we have approximately 4,000 women in total in the three LibiGel Phase III studies.

CEO CFO: What is the market opportunity for LibiGel?

Mr. Simes: There are different ways to look at the market. The erectile dysfunction market in the U.S., which is the market for Viagra, Levitra, and Cialis, is about \$2 billion a year. Based on publications on women's self-reporting of how many women

suffer from low sexual desire, or low sexual activity, we believe the market for women is at least \$2 billion. However, there is another very important consideration. Last year in the U.S., there were 4 million testosterone prescriptions, written off-label by physicians for women. That is, they are

using men's testosterone or they are using other products that are not FDA-approved to treat the condition. In any event, doctors already are prescribing and women already are using testosterone for this indication, and the 4 million depending on the pricing would result in a \$1 to \$2 billion potential for LibiGel. Now the question is why do we need LibiGel? Those other products are not FDA-approved or clinically tested, so the safety has not been proven and most importantly there is no way of knowing what the effective dose is. Therefore, in our primary research, doctors tell us that, if and when LibiGel is approved, they will switch about 96% of those women using testosterone today to LibiGel. That represents well over a \$1 billion opportunity for us.

CEO CFO: So people are waiting!

Mr. Simes: We learn from our physician surveys that only about 30% of menopausal women are treated to-

day, so those 4 million off-label prescriptions really are only about 30% of the women who have a need. Therefore, we think the market can grow from the 4 million current off-label prescriptions. The other part of it is that the demand is dramatic as evidenced by our own clinical studies. When we advertise for women to enter our clinical studies, the phones ring off the hook and we have hundreds of thousands of visits to our website. Therefore, we know that there is a market ready for an FDA-approved product.

CEO CFO: What is the financial picture like for BioSante today?

Mr. Simes: We have reported that at the end of December of 2010 we ended the year with a little over \$38 million in the bank. We have been very successful in the last year or two at raising significant sums of money to help support the LibiGel program. This is in an environment where things are looking better now. In fact, on March 4, 2011 we announced a funding of \$25 million in a registered direct placement. Therefore, we are in very good financial shape and we are implementing the LibiGel plan. We are spending about \$3.5 or \$4 million

a month on the clinical studies and as I mentioned, we hope to submit the new drug application in early 2012 for an approval in 2012.

CEO CFO: Do you have other products in the works as well?

Mr. Simes: We do. LibiGel is really our focus. The other products mostly are being developed on an out-license basis, for example our Bio-T-Gel™, which is a male testosterone product. The product already is licensed to Teva Pharmaceuticals, which is one of the largest generic companies in the world, although they have a very big branded side of their business as well. We are hoping to be able to announce an FDA submission by Teva of our Bio-T-Gel in the early part of 2011. That would be a very big opportunity for us because they are developing it at no cost to us, they will market it at no cost to us, and then they will pay us on a royalty basis. That is one example of how we have been able to maximize the value of some of our products throughout license, so they are being developed for eventual upside for our stockholders at no cost to BioSante.

CEO CFO: In closing, why should potential investors choose BioSante Pharmaceuticals?

Mr. Simes: BioSante is a very interesting opportunity and is a company on the leading edge of a very important unmet medical need. Female sexual dysfunction is a very critical issue and again I will repeat, thirteen years after Viagra was approved for men, women still don't have an option for their sexual health. To the extent that women want to be treated, we think a product should be available. It is all about choice for women. We are developing LibiGel, which is in late stage, Phase III clinical development with an approval on the horizon. We believe the upside for our stockholders is dramatic. We have the money in the bank to implement the plan as I have described, as well as the people to take this product through to an FDA approval. They have a proven track record as evidenced by our Elestrin approval. LibiGel is being dealt with by the same division at the FDA, The Division of Reproductive and Urologic Products, as was Elestrin. In summary, we believe BioSante is well positioned for increasing value for our stockholders.

The logo for BioSante Pharmaceuticals features the word "BioSante" in a large, bold, blue sans-serif font. Below it, the word "Pharmaceuticals" is written in a smaller, grey sans-serif font. The entire logo is centered horizontally.

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