Jason N. Butler, PhD
jbutler@jmpsecurities.com
(212) 906-3505

Biotechnology – Initiation March 16, 2011

BioSante Pharmaceuticals, Inc. (1,2)

Clear Timelines Set for LibiGel; Initiating Coverage with Market Outperform Rating

MARKET OUTPERFORM BPAX $1.79

Price	$1.79
Target Price	$5.00
52-Wk Range	$1.29 - $2.50
Shares Out. (M)	93.6
Market Cap. (M)	$167.5
Average Daily Vol. (000)	1,964
Float (M)	65.8
Secular Growth Rate	--
LT Debt (M)	$22.0
Cash (M)	$66.2
Enterprise Value (M)	$123.4
Cash/Share	$0.71

FY: Dec		2010E	2011E	2012E
Revenue (M)	1Q	$2.3A	$0.0	--
	2Q	$0.0A	$0.0	--
	3Q	$0.1A	$0.0	--
	4Q	$0.0	$0.0	--
	FY	**$2.3**	**$0.0**	**$0.0**

		2010E	2011E	2012E
EPS	1Q	($0.19)A	($0.13)	--
	2Q	($0.17)A	($0.14)	--
	3Q	($0.16)A	($0.14)	--
	4Q	($0.13)	($0.12)	--
	FY	**($0.65)**	**($0.52)**	**($0.40)**
	P/E	NM	NM	NM
	Previous FY	NE	NE	NE
	CY	**($0.65)**	**($0.52)**	**($0.40)**
	P/E	NM	NM	NM

NC indicates no change to previous estimate. NE indicates no previous estimate.

Source: Company reports and JMP Securities

INVESTMENT HIGHLIGHTS

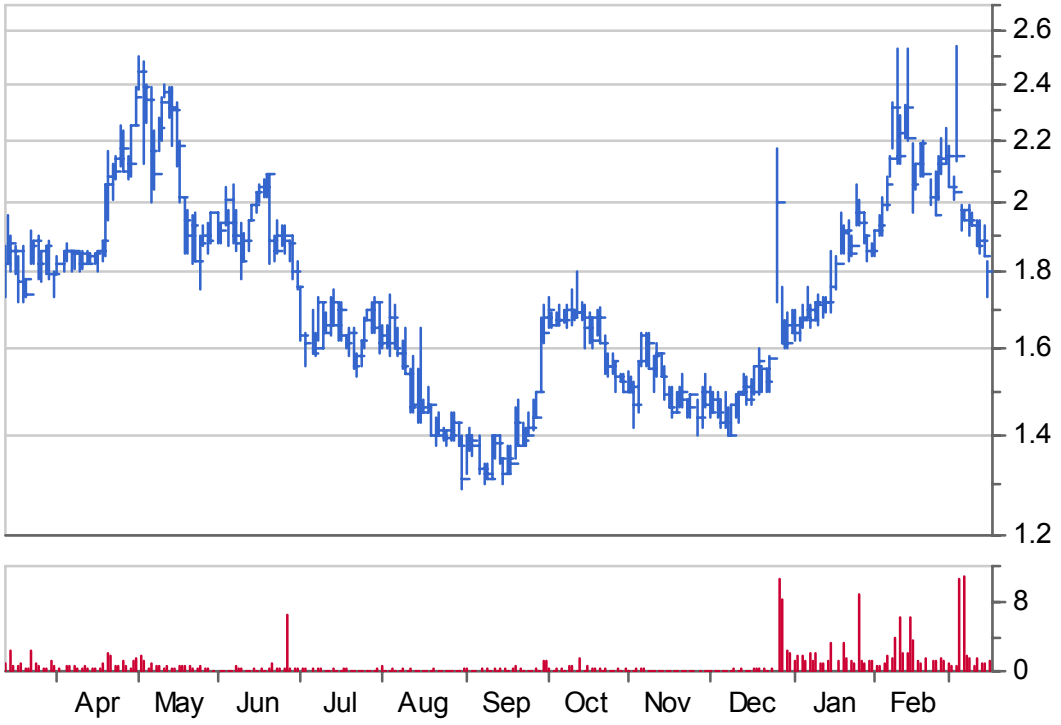
- **We are initiating coverage on BioSante Pharmaceuticals with a Market Outperform rating and price target of $5.** We view BioSante as an underfollowed and undervalued microcap company with a late-stage development asset that has better than average clinical risk. BioSante's lead product candidate is LibiGel, a proprietary formulation of testosterone delivered through the skin being developed for the treatment of female sexual dysfunction, for which there is currently no approved therapy. We believe that with clarity emerging on timelines for key value-driving LibiGel catalysts, institutional interest will increase and the market inefficiency in the current valuation can begin to resolve. Our $5 price target is derived by applying a 5x multiple to our base case projection for LibiGel sales of $422MM in 2016, discounted by 30% per year.
- **Efficacy trials have high probability of success.** Results from two pivotal Phase III efficacy trials for LibiGel are expected in 4Q11, and, in our view, there is a high likelihood of success for these trials based on the large amount of controlled clinical data, including a Phase II trial conducted by BioSante, supporting the benefit of testosterone in women with Hypoactive Sexual Desire Disorder (HSDD).
- **Long-term safety study expected to confirm lack of overt risk.** The rate limiting step for the LibiGel NDA submission is unblinding of a long-term safety trial, which is currently enrolling up to 4,000 women and has so far enrolled approximately 2,900 women, representing more than 3,000 women-years of exposure. We assume a base case scenario where the NDA can be submitted in mid 2012 and believe that the trial will achieve its initial aim of ruling out an unacceptable level (2x) of cardiovascular and breast cancer risk compared to placebo. In our view, these potential risks for testosterone are not well supported by clinical evidence and the FDA's concern was driven primarily by increased risks associated with estrogen and progestin hormone replacement therapy.
- **Market potential attractive assuming increasing off label use.** While we anticipate the LibiGel label to be at first limited to surgically menopausal women (the population assessed in the efficacy trials), we expect the drug's use to extend beyond this to naturally menopausal women (included in the long-term safety study). Data support testosterone's efficacy treating HSDD in surgically and naturally menopausal women. In addition, market research funded by BioSante indicates that physicians will not differentiate between these women when determining an appropriate patient.

FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO THE JMP FACTS AND DISCLOSURES SECTION

COMPANY DESCRIPTION

BioSante Pharmaceuticals is a biopharmaceutical company focused on developing hormone replacement therapy products to treat men and women. The company's lead product candidate is LibiGel, a transdermal testosterone gel formulation being developed for the treatment of low sexual desire in women. LibiGel is currently being evaluated in three Phase III trials, and the company intends to submit the NDA for the candidate in 2012. BioSante's pipeline includes Bio-T-Gel, a testosterone gel for male hypogonadism that was licensed to Teva Pharmaceuticals, and an oral contraceptive licensed to Pantarhei Bioscience, currently in Phase II development. The company previously developed and secured FDA approval for Elestrin, a transdermal estrogen gel for the treatment of hot flash symptoms associated with menopause, currently marketed in the U.S. by Azur Pharma. Additionally, the company holds rights to a portfolio of cancer vaccines that was acquired through the merger with Cell Genesys in 2009.

FIGURE 1: BioSante Pharmaceuticals Historical Price Chart



Source: FactSet

UPCOMING CATALYSTS

2Q11 - Sixth independent data monitoring committee safety review of LibiGel BLOOM trial
4Q11 - Results from two LibiGel Phase III efficacy trials
2012 - Submit LibiGel NDA

VALUATION

We value BioSante based on our projections for LibiGel sales in the U.S. alone and currently do not include the company's pipeline assets, specifically Bio-T-Gel and the GVAX cancer vaccine portfolio, which we conservatively view as upside to our valuation.

Our base case valuation scenario assumes that LibiGel will be used in surgically menopausal women and, to a limited extent, off-label for treatment of naturally post-menopausal women. Under this scenario, we project that LibiGel will be approved and launched in the U.S. in 2H13 and will achieve sales of $390MM in 2016, the third full year from launch. We derive our $5 price target by applying a 5x multiple to our 2016 sales projection, discounted by 30% per year to the end of 2011. Our price target assumes our current estimate for fully diluted shares outstanding at the end of 2011 of approximately

130 million shares, which includes approximately 24 million warrants with an exercise price below our objective.

We estimate a current pro forma cash balance of approximately $55MM, or approximately $0.45 per fully diluted share. In addition, the company currently has convertible notes outstanding related to the merger with Cell Genesys. The principal outstanding for these notes is approximately $22MM, resulting in a net cash position of approximately $33MM, or $0.27 per share. We note that our current projections for cash burn include an equity financing in 4Q11 following release of results from the LibiGel efficacy trials, which we view as a significant catalyst not only for valuation but also investor demand. We assume that the company sells seven million shares at $4 per share. We do not include our projections for net cash position in our price target calculation; however, we do include the additional dilution in our estimate of year-end 2011 shares outstanding.

FIGURE 2: Absolute Valuation

	Sales	Revenue year	Profit share	Multiple	Discount rate	Current value	Current value per share
LibiGel							
Base case	**422**	**2016**	**100%**	**5**	**30%**	**594**	**$4.57**

Source: JMP Securities estimates

LibiGel Revenue Model

According to data from the National Health Statistics Reports, in 2007 there were 366,000 surgical menopause (oophrectomy and salpingo-oophrectomy) procedures in U.S. women (over the age of 15 years). We assume that the prevalence of surgically menopausal women in the U.S. is approximately 10.5 million in 2011 (Howe, American Journal of Public Health, 74:6, 1984). We then assume that the addressable patient population for women with HSDD is 7.4% and 7.0% for surgically and naturally menopausal women, respectively (see our discussion on the HSDD commercial opportunity for further details, pages 5-8). Based on these assumptions, we determine that there are approximately 800,000 surgically menopausal and 2.2 million naturally menopausal women eligible for treatment with LibiGel in 2011. Our model includes U.S. population growth of slightly under 1% per year, in line with U.S. Census Bureau estimates.

We have modeled LibiGel sales under three scenarios, varying penetration into the surgically and naturally menopausal populations. Our worst case scenario assumes that the drug is used only for the on-label surgically menopausal population, reaching a peak penetration of 27%, with no off-label use in naturally menopausal women. Our base and best case scenarios maintain our penetration projection of 27% in surgically menopausal women but then includes increasing off-label penetration in naturally menopausal women reaching peak levels of 8% and 18%, respectively. For all scenarios, we assume a price at launch of $240 per month and assume that, on average, women remain on therapy for 10 months of the year. In 2021, the final full year before patent expiration, we project U.S. LibiGel sales for our worst, base, and best case scenarios of $324MM, $651MM, and $1,114MM, as shown in our LibiGel revenue model on page 18 (Figure 12).

In addition, we assessed the impact of extending marketing exclusivity beyond the current patent expiration date in June 2022 through to June 2026, which takes into consideration either patent term extension for the currently issued U.S. patent or additional protection from a pending patent application covering formulations and methods of use, filed in May 2026. We conducted an NPV scenario analysis to determine the impact of extending marketing exclusivity from 2022 to 2026 on each of our three scenarios for market penetration. Extended market exclusivity would present upside of 22-29% of our base case assumptions.

KEY INVESTMENT POINTS

BioSante has spent a long time under the radar; however, we expect the next 12 months to be transformational. BioSante's lead product candidate is LibiGel, currently in Phase III development for the treatment of hypoactive sexual desire disorder (HSDD) in women, a condition for which there are no approved products. We believe this asset presents a favorable investment risk profile with lower than average clinical risk and regulatory clarity that has emerged defining a path to market in new therapeutic indication. While the lack of precedent for the commercial setting presents a degree of uncertainty, we believe that increasing awareness among physicians and the general public will assist in driving patient demand. We view the current valuation, with a fully diluted enterprise value of less than $200MM, as an attractive entry point for a Phase III product candidate that generates what we view to be potentially a blockbuster market opportunity. Moreover, we believe that visibility on timelines

to key catalysts is continuing to emerge and can drive broader institutional investor interest over the coming 12 months.

Demonstrated management success with Elestrin development and approval. Previously, BioSante developed Elestrin, a transdermal estrogen therapy for the treatment of moderate-to-severe menopausal hot flashes, for which the company secured FDA approval in December 2006. The approval of Elestrin was achieved following the first cycle regulatory review (10 month review period) despite the negative overhang of the Women's Health Initiative (WHI), which demonstrated increased risks with hormone replacement therapy (estrogen and progestin). In our view, the approval of Elestrin supports management's ability to effectively work with the FDA's Reproductive Health Drugs Division (the same division that is responsible for regulatory review of LibiGel) and execute on development and regulatory strategy. Furthermore, in contrast to many areas of the FDA, the Reproductive Health Drugs Division has maintained stability over the past decade, which, in our view, makes the Elestrin success a relevant advantage. Elestrin is currently marketed by Azur Pharma, and, in December 2009, BioSante divested all royalty rights to the product. BioSante retains rights to receive up to $140MM in sales-based milestone payments from Azur.

Completion of enrollment in efficacy trial sets clock for key value-driving catalyst in 4Q11. At the end of February, BioSante announced completion of enrollment in the first of two efficacy trials for LibiGel. Both trials are evaluating LibiGel compared to placebo in approximately 500 surgically menopausal women. We expect completion of enrollment in the second trial in the near term. The treatment duration for these trials is six months, and therefore we anticipate top line data release for both trials in 4Q11. In our view, positive results from these trials are a significant value-driving catalyst for the stock.

Assessing efficacy, three key metrics. The FDA has provided guidance that co-primary endpoints for therapeutic development programs in HSDD should assess the number of satisfying sexual events, averaged over a four week period at the end of a six month treatment duration and the impact on sexual desire. Furthermore, a key secondary endpoint that must be assessed is the impact of therapy on a woman's distress related to her condition. We believe that there are multiple examples where the FDA's stance on the requirements for demonstrating efficacy with an HSDD therapy has been reiterated. We specifically highlight the Special Protocol Assessments (SPAs) granted by the FDA for the LibiGel program as well as statements made at FDA Advisory Committee meetings for two previous development programs in HSDD, Proctor and Gamble's (P&G's) Intrinsa (testosterone transdermal patch) and Boehringer Ingelheim's flibanserin. In our view, the LibiGel trials have been well designed and validated by the FDA through three issued SPAs and, if successful, will support regulatory approval.

Benchmarking efficacy; looking for an increase of one SSE per month. In our view, the most positive takeaway from the Advisory Committee meeting for Intrinsa, other than the concurrence that HSDD was an unmet medical need that would benefit from new therapies, was the vote strongly in favor (14-3) of the drug's efficacy. The benefit with Intrinsa was a statistically significant increase of one SSE over a four week period. While the LibiGel Phase II trial demonstrated a much greater treatment effect, with an average increase of 3.4 events above the effect of placebo, we maintain a conservative stance given the small size of this trial (n=46) and would view an increase of one or more SSEs over placebo as both sufficient for FDA approval and commercial viability. In addition to the primary efficacy analysis, we will be looking for responder rates (the proportion of patients who achieve increases in the number of SSEs from baseline) with LibiGel to be statistically superior to placebo.

Limited evidence pointing to risks with testosterone, but FDA needed to make sure. BioSante is currently conducting a large, long-term safety trial for LibiGel focused on assessing the potential for increased risks for cardiovascular events and breast cancer. This trial was required by the FDA to address potential concerns with testosterone therapy following the negative results from the WHI. In light of the WHI data, the FDA became concerned that these risks have not been assessed with testosterone in women in sufficient numbers or duration of therapy, even though no overt signal of risk emerged from these studies. We note that a criticism of the Intrinsa trials by the FDA was an apparently inadequate ethnic representation. The FDA stated that "African-Americans make up 13 percent of the U.S. population, but only 6 percent of the study population". We believe that this potential criticism has been addressed in the LibiGel safety trials where currently approximately 10% of the women enrolled are black.

Testosterone safety concerns are predominantly hypothetical. Testosterone is known to have adverse effects relating to over-stimulation of the androgen system; however, evidence is supportive that these effects are unlikely to be concerning, both in terms of frequency and severity, at the low levels involved with LibiGel treatment. In terms of cardiovascular and breast cancer risk, while there is not compelling data for an overt signal of risk with testosterone, there have not previously been well

controlled trials to assess the potential for a low absolute level of risk, which may theoretically have a long latency from exposure to occurrence. It may also be relevant to consider whether testosterone extenuates the risk of estrogen and that a small amount of testosterone is converted (aromatized) to estrogen. During the December 2004 Advisory Committee for P&G's Intrinsa, the FDA stated that its biggest concern was not evidence of risk but that "we simply don't have enough data on women taking testosterone on a chronic basis to be able to look into a crystal ball and see what we may see in a population".

Visibility increasing on timelines for safety study. BioSante is continuing to enroll patients in the long-term safety study towards a target of 4,000 menopausal women. It is possible that the Data Monitoring Committee (DMC) could halt enrollment early based on their unblinded review of data (the company remains blinded) indicates that there is a high likelihood of achieving a statistically significant outcome (<90%); however, we currently maintain a conservative view that full enrollment will be complete by the end of 3Q11. As agreed with the FDA, the company can then submit the NDA when there is a minimum average of 12 months treatment duration for the enrolled patient population. The longest period of time to NDA submission is therefore 12 months following the announcement of the last patient enrolled (i.e., in 4Q12). In our view, it is possible for the company to submit the NDA earlier than this, when the average duration of exposure exceeds 12 months, and, at present, assume NDA submission in mid 2012. We note that, as of the most recent DMC review, the average duration of treatment is approximately 12.5 months (n ~2,900), and we assume that, following completion of full enrollment (4,000 women) in 3Q11, it would take a further six months for the average duration of the entire trial population to exceed 12 months.

INVESTMENT RISKS

Clinical risk. BioSante's development candidates could fail to generate expected results in current or future clinical trials.

Regulatory risk. The FDA, and/or other ex-U.S. regulatory agencies, could reject any of the firm’s, or its partners', future regulatory filings or require additional studies prior to granting approval. We note that no product has been previously approved for the treatment of female sexual dysfunction in the U.S.

Commercial risk. If successfully developed, BioSante's products may face competition both from approved products and also potentially from new product candidates in development by biotechnology and pharmaceutical companies.

Balance sheet risk. The expenses associated with drug development are high. It is possible that the company will return to the capital markets to secure additional financing to fund current or future development programs. As of December 31st, 2010, BioSante had approximately $39MM in cash and equivalents, which we do not believe will be sufficient to fund operations through profitability.

FEMALE SEXUAL DYSFUNCTION

Female sexual dysfunction (FSD) is a complex group of sexual disorders affecting women of all ages. A classification of the disorders defines four main sub-types of disease relating to low desire, diminished arousal, orgasmic difficulties, or painful intercourse. The disease can be attributed to multiple causes including hormonal imbalances, underlying medical conditions (both physiological and psychological), concomitant medications, or a combination of these. FSD has been an under-treated condition for many years, largely driven by the fact that there are currently no pharmacological therapies approved by the FDA for the treatment of FSD-related disorders. However, demonstrated success in treating erectile dysfunction in men has generated interest in the opportunity to address sexual disorders in women, and FSD is now viewed as not only a relevant unmet medical need but also an attractive commercial prospect.

Hypoactive Sexual Desire Disorder
Hypoactive Sexual Desire Disorder (HSDD) is a sexual desire disorder that is defined as a deficiency or absence of sexual fantasies and desire for sexual activity. Importantly, a woman must experience personal distress by this diminished desire in order to be diagnosed with HSDD. Finally, it is necessary that the disorder is not better accounted for by a general medical, other psychiatric, or a substance or drug-related condition. There are data that androgens such as testosterone have some beneficial effect in this condition, and, as such, BioSante is developing LibiGel, a transdermal testosterone for this indication.

HSDD Commercial Opportunity

Reports indicate that the number of women affected by FSD and HSDD is large; however, accurately determining the women who can benefit the most from new therapies and the true market potential is more challenging. The multi-factorial nature of the disease as well as the historical stigma further complicate this analysis.

There is, in our view, growing recognition both from treating physicians and regulatory agencies that HSDD is a real unmet medical for which women could benefit from therapeutic options. A study published in the July 2009 issue of The Journal of Sexual Medicine reported that, according to an independent survey, 80% of physicians believe there is a need or great need for an FDA-approved treatment for women with HSDD. In addition, 90% of these doctors would prescribe an approved product rather than currently available therapies used off-label. Below, we also note comments from two FDA advisory committees that have reviewed product candidates for this indication during the past six years for Proctor and Gamble's Intrinsa and Boehringer Ingelheim's flibanserin (neither of which received favorable panel recommendations or subsequent marketing approval).

Intrinsa FDA Advisory Committee Meeting - December 2, 2004

"And the Division did designate this review a priority review, which means it was given a six-month review clock. We did so because there are no products approved for female sexual dysfunction, and a product that successfully treats this disorder could have a major impact on a woman's quality of life."

Donna Griebel, Deputy Director of the Division of Reproductive and Urologic Drug Products

Flibanserin FDA Advisory Committee Meeting - June 18, 2010

"In summary, it is identified that HSDD is a real condition. However, the diagnosis is still challenging."

"We also, though, bring to the point that, indeed, this is a significant need for women and finding a medication that will benefit women is critical. And, finally, that based on the data, that indeed we need to continue to look at ways for treating this disorder."

Julia Johnson, M.D., Professor and Chair Department of Obstetrics and Gynecology, University of Massachusetts Medical School and Acting Chair of the Advisory Committee for Reproductive Health Drugs

Data from the U.S. National Health and Social Life Survey estimate that the prevalence of FSD exceeds 40% of all women in the U.S. (Laumann et al., *JAMA* 281: 6, 1999). Within the overall population analyzed, low sexual desire was found to be prevalent in 22% of the female participants, arousal problems occurred in 14% of the women, and sexual pain was present in 7% of the women surveyed.

A limitation of resources such as U.S. National Health and Social Life Survey is that they do not take into account confounding factors that may contribute to low sexual desire, and these factors may diminish or eliminate any benefit from treatment for HSDD, most notably, we believe, depression. Therefore, it is likely that such databases overestimate actual prevalence of FSD and HSDD. We, therefore, have attempted to further characterize the eligible treatment population and have identified three sources estimating prevalence of low sexual desire accompanying personal distress, the key attributes of the HSDD definition:

1. WISHeS (Women's International Study of Health and Sexuality, sponsored by P&G during the development of Intrinsa)
2. A national probability sample of U.S. women (West, et al., Arch Intern Med. 168: 13, 2008)
3. The PRESIDE study (U.S. Prevalence of Female Sexual Problems Associated with Distress and Determinants of Treatment Seeking

Based on these databases, we estimate that the prevalence of low sexual desire with accompanying personal distress is increased in surgically menopausal women. Two of the three studies support a prevalence of HSDD in the range of 11-12.5%, and all studies indicate that the target patient is between 40 and 59 years of age. Most importantly, we believe, for determining the patients with the highest likelihood of seeking, and benefiting from, treatment with a novel HSDD therapy, the prevalence of the condition when accounting for distress is approximately 7% in women aged 40 and over. Summaries of the results from these studies, stratified both by menopause status and by age, are provided in figures 3 and 4.

FIGURE 3: HSDD Prevalence by Menopause Status

	WISHeS - US	National Sample	PRESIDE	PRESIDE (excl depression)
Sample size	952	2,207	31,364	31,364
HSDD prevalence				
Premenopausal	13.5%	7.7%	8.6%	6.1%
Naturally postmenopausal	9.1%	6.6%	9.7%	6.5%
Surgically postmenopausal	17.5%	12.5%	10.9%	7.4%

Source: Company reports

FIGURE 4: HSDD Prevalence by Age

	WISHeS - EU	WISHeS - US	National Sample	PRESIDE	PRESIDE (excl depression)
Sample size	2,467	952	2,207	31,364	31,364
Age					
30-39yrs	6%	19%	8%	10%	6%
40-49yrs	10%	15%	9%	11%	7%
50-59yrs	13%	13%	9%	13%	7%
60-69yrs	12%	12%	6%	10%	7%

Source: Company reports

WISHeS

The Women's International Study of Health and Sexuality (WISHeS) was funded by P&G during the development of Intrinsa and was specifically designed to better understand HSDD in women. In this study, more than 4,500 women in the U.S. and Europe between the ages of 20 and 70 were surveyed, including 520 surgically and naturally menopausal women with partners. The results showed that women with HSDD do engage in sexual activity but are significantly less likely to initiate sexual activity. Women with HSDD reported feelings of low self-esteem, shame, and failure as well as lower levels of social functioning and emotional and mental health. Results from the U.S. sample of the WISHeS study were published in 2006 in the journal Menopause (Leiblum et al., *Menopause* 13:1, 2006). As per WISHeS, we estimate the prevalence of HSDD in surgically menopausal women at present to be 18% or approaching two million women in the U.S.

National Probability Sample

In 2008, West et al. published results from a cross-sectional study that included more than 2,200 women aged 30 to 70 years who had been in stable relationships for at least three months (West et al. *Arch Intern Med* 168:13, 2008). The study found that while the prevalence of low sexual desire was as high as 36%, the accompaniment of distress was present to a lesser extent (8.3% in the overall population). For the 1,920 women for whom full data were available to make a diagnosis, the prevalence of HSDD was 8.3%. When stratified by menopause status, the prevalence of HSDD was highest in women who had undergone surgical menopause, at 12.5%. This compares to the prevalence of HSDD in naturally menopausal women of 6.6%.

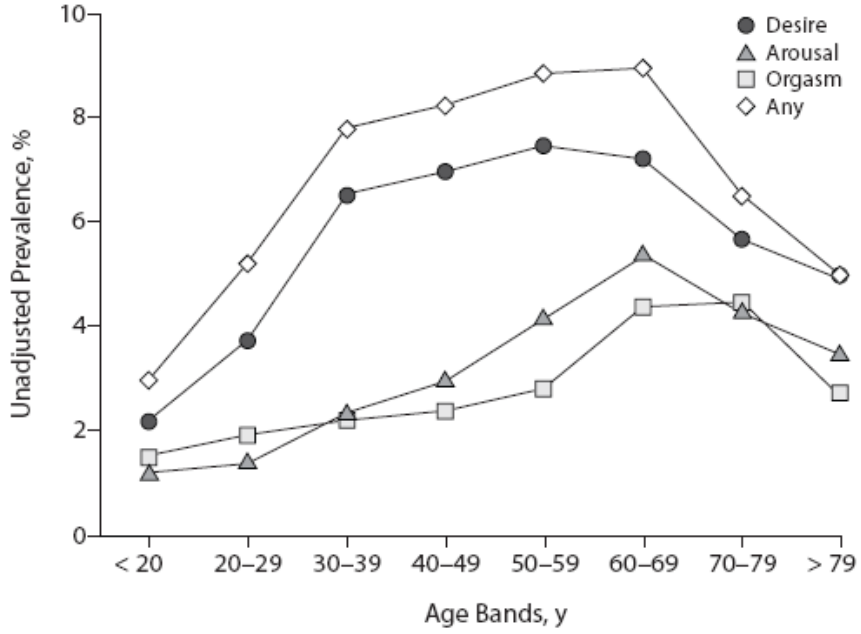
The importance of distress in the diagnosis of HSDD is highlighted by this study when the results are stratified by age. The study showed that the prevalence of low sexual desire increased with age from 25% in women 40-49 years to 38% in women 50-59 years and peaking in women 60-70 years at 61%. However, the prevalence of HSDD peaks in women aged 40 to 59 years but then declines in women after the age of 60. In our view, the distinction of low desire in the presence of distress is likely an important determinant in women seeking treatment for HSDD. We also note that although the sample size is small (270 women), the prevalence of HSDD increased to 21% in women currently suffering from depression.

PRESIDE

Similar to the National Probability Sample, the PRESIDE (Prevalence of Female Sexual Problems Associated with Distress and Determinants of Treatment Seeking) study was a cross sectional, population-based survey of women in the U.S. (Shifren et al. *Obstet Gynecol* 112:5, 2008). However, it considered a much larger sample size than the previous studies (~30,000 women). The results from this study largely supported the National Probability Sample, determining that the prevalence of HSDD in surgically menopausal women was approximately 11%. The study also supported the finding that HSDD prevalence was higher in women 45-64 years than in younger or older women. Again, consistent with the National Probability Sample, depression was associated with symptoms of low sexual desire and distress.

The information provided by these three studies offers useful insights into the potential market for an HSDD treatment; however, it is possible that they are limited in that they do not correct the potentially confounding factor of depression. Johannes et al. addressed this issue by analyzing data from the PRESIDE study to estimate the prevalence of HSDD while accounting for concurrent depression (Johannes et al., *J Clin Psychiatry* 70:12, 2009). The analysis found that approximately in 40% of women a reported sexual problem could be attributed to concurrent depression. When adjusting for depression, it was shown that the prevalence of a sexual problem associated with distress was 7.6%, compared to 12.1% irrespective of depression. For HSDD, accounting for depression lowered the overall prevalence from 10% to 6.3%. In surgically menopausal women, adjusting for depression resulted in an HSDD prevalence of 7.4%. When adjusting for depression, it was shown that the peak prevalence in desire disorder was observed in older women where prevalence was approximately 7% in women aged 50-69 years, as shown in Figure 5.

FIGURE 5: HSDD Prevalence in the Absence of Depression



Source: Johannes et al. J Clin Psychiatry 70:12, 2009

TESTOSTERONE FOR HSDD

Hormones play a key role in human development and proper bodily function. The sex hormones consist of three classes: progestogens, androgens (including testosterone), and estrogens. While testosterone is a major male sex hormone, it is also produced by women and is believed to be a significant influencing factor in sexual desire. As well as acting directly to increase blood flow to the vagina, testosterone acts centrally through receptors in the brain.

As women age, the production of sex hormones by the ovaries, which account for 60% of the estrogen and 50% of androgens in the body, decreases. In postmenopausal women, the level of testosterone in the blood decreases to approximately half compared to that present in a young woman (mid 20s). Additionally, oopherectomy, surgical removal of the ovaries, can accelerate this decrease in younger women. Decreased levels of testosterone in women have been linked to fatigue, diminished sense of well being, and decline in libido and sexual functions, such as decreased sexual arousal, genital stimulation, and orgasm in women. Treatment with testosterone therapy has been shown to positively impact female sexual response, including desire, arousal, and orgasm.

Several testosterone treatments are available for men suffering from testosterone deficiencies, such as hypogonadism. Conjugate and biologically equivalent forms of the hormone are available in oral, transdermal, or topical formulations, and specialty pharmacies can meet demand for specific concentration parameters. In addition, oral formulations of dehydroepiandrosterone (DHEA), a pre-hormone to testosterone, are available over the counter as food supplements; however, studies with DHEA have not yielded consistent results.

Transdermal Testosterones
Androderm (Watson Pharmaceuticals), Androgel (Abbott Labs), Axiron (Eli Lilly), Striant (Columbia Laboratories), Testim (Auxilium Pharmaceuticals), Fortesta (Endo Pharmaceuticals)

These testosterone treatments are used off label in women to improve sexual desire, vaginal dryness, and decreased vaginal sensation. However, there can be problems associated with the off label use of these formulations intended for use in men, with potential adverse health implications. This is primarily due to the fact that men normally have much higher levels of endogenous testosterone than women and the available male products do not adequately enable accurate dose administration for women. The amount of free testosterone in normal young men is approximately 3%, higher than the 1-2% in women. The most common result from the off label use of male testosterone products is that too much hormone is administered to women bringing known hyperandrogenic risks including acne, hitsutism (excessive hairiness), alopecia (hair loss), clitoral enlargement, and voice deepening. However, it is generally accepted that these effects are dose related and at lower doses are substantially less common and primarily mild in nature.

Hypothetical safety concerns with testosterone in women
Negative results from the Women's Health Initiative (WHI), first released in 2002, have had a profoundly negative impact on the hormone replacement market and specifically the market for oral estrogen and progestin treatments. It is widely accepted that hormone replacement therapy is an effective treatment for menopausal symptoms; however, the WHI raised safety questions relating to increased risks for cardiovascular disease and bone loss and cancer. Studies assessing both estrogen therapy alone and in combination with progestin were stopped early due to unfavorable risk/benefit analysis of interim results for each treatment when compared to placebo.

There are three topics of hypothetical concern that have been raised with regards to testosterone, cardiovascular risk, breast cancer risk, and potential liver damage, of which the latter has predominantly been dismissed as risk when the hormone is delivered transdermally. The WHI did not show an increased risk/cause for concern with testosterone, but it did broadly illustrate the potential risk with hormone therapy in postmenopausal women. More importantly, it demonstrated that randomized, controlled trials may demonstrate different results than observational studies, and it is widely accepted that, whenever possible, randomized data are more reliable in defining risk. While there is no compelling evidence for these concerns, the negative overhang of the WHI results led to a regulatory change with the FDA determining that long-term safety data would be required for approval of a testosterone product for use in women.

Cardiovascular effects
The WHI data provided evidence for an increased risk of cardiovascular events with estrogen and progestin therapy. This risk is of particular focus as cardiovascular disease is the leading cause of death in postmenopausal women. There was no overt signal of risk with testosterone therapy in woman, although the data were from a more limited patient pool. It is also of note that there is no evidence that men have higher rates of coronary disease because of their circulating androgens, and it has not been possible to correlate circulating androgens to the risk of cardiovascular disease. However, data from the WHI did indicate that women in the highest quartile of androgen levels had an increased risk of developing some kind of cardiovascular event. It is also of note that testosterone can be aromatized to estrogen, for which there are known concerns, as highlighted by the WHI studies. Perhaps more so than questioning whether testosterone alone increases cardiovascular risk, it is maybe relevant to consider whether it can accentuate the thrombogenic potential of estrogen. In fact, the FDA has previously stated that an "overarching concern" in evaluating the safety of a transdermal testosterone product in surgically menopausal women is that the target population may also be receiving concomitant estrogen therapy. Finally, while metabolic syndrome and polycystic ovarian syndrome are known to involve increased androgen levels and both conditions are associated with increased cardiovascular risk, it is not known whether testosterone is driving this risk or is a secondary effect.

There is a greater, although still limited, knowledge base covering the effects of androgens on biomarkers of cardiovascular risk. While the data are by no means conclusive, they indicate that testosterone has a neutral impact. In terms of lipids, androgens have been demonstrated to reduce HDL cholesterol; however, they appear to be neutral to LDL cholesterol and, as such, would not likely pose a substantial risk. Additionally, androgens have a beneficial effect lowering triglyceride levels. Vascular reactivity and plasma viscosity have also been related to increased cardiovascular risk, and although the data are limited, testosterone is thought to be possibly beneficial. There is little data on the impact of testosterone on changes in fasting glucose or in insulin sensitivity.

Endometrial and breast effects
The suggestion of increased risk of endometrial and breast cancer is based on epidemiological studies that indicate a relationship between increased endogenous global hormone levels and the development of disease. In addition, androgen receptors are found in 50-90% of breast tumors, and therefore it is mechanistically possible for testosterone to act directly to stimulate breast epithelium. It is also possible that as testosterone may be aromatized to estrogen, which in turn acts on breast tissue. However, in women, there is no compelling evidence of increased breast cancer incidence related to exogenous testosterone treatment. Furthermore, the epidemiological evidence suggesting a relationship between high endogenous testosterone and breast cancer is limited and has not yet been supported or refuted by well-controlled studies.

Liver function effects
Prolonged use of orally administered androgens, such as methyltestosterone, has been associated with serious liver damage. Alkylation, required to make testosterone orally bioavailable, places increased stress on liver function. In addition, the liver is the major site of testosterone metabolism, and therefore it is theoretically possible for testosterone clearance to be reduced in patients with impaired liver function. However, testosterone delivered transdermally has not been shown to cause these adverse effects.

LIBIGEL DEVELOPMENT PROGRAM

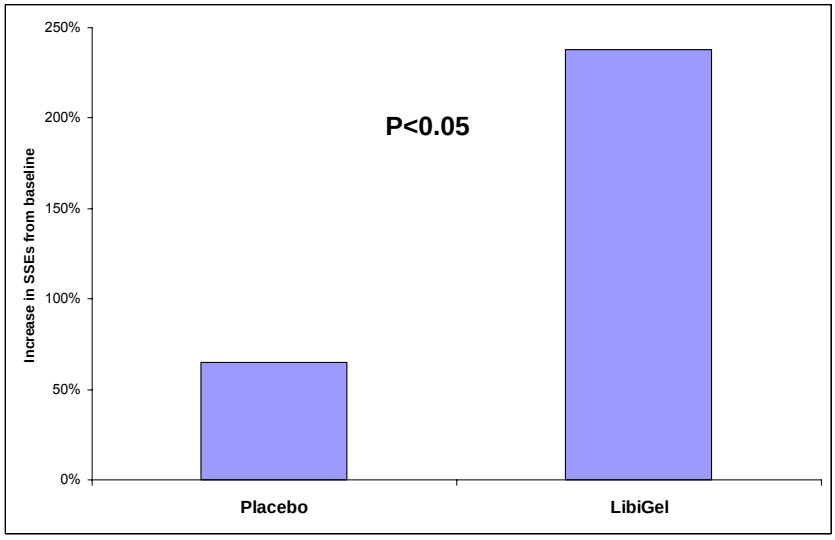
LibiGel is a once-daily, transdermal testosterone gel formulation that is being developed for the treatment of HSDD in surgically menopausal women. The gel is quickly absorbed (within minutes) through the skin after application on the upper arm, without leaving a trace residue or odor, and provides for continuous delivery of testosterone into the blood stream over 24 hours in a non-invasive and painless manner.

License agreements
LibiGel is administered through a gel delivery technology developed by Antares Pharmaceuticals and in licensed by BioSante. Under the terms of the license agreement, BioSante is required to pay Antares milestone payments and royalties, at a low single digit rate, on net sales of LibiGel in the U.S. and several international markets. BioSante has not licensed the right to the gel delivery technology in the EU or Japan.

Intellectual property
There is currently one issued patent covering LibiGel that is expected to expire in June 2022, excluding potential patent term extensions, which we would expect to provide a further five years marketing exclusivity. The patent (U.S. patent number 7,198,801) broadly covers formulations for transdermal and transcucosal administration of hormones including estrogen, progestin, and testosterone. A second patent application is currently pending including claims of formulations and methods to treat symptoms of hormonal disorders with transdermally administered testosterone. This patent application was filed in May 2006 and the application number is 11/441,311.

Phase II results
Preliminary evidence of LibiGel's efficacy was provided by a 46 patient Phase II trial completed in 2004. This was a double blinded, placebo-controlled trial that enrolled surgically menopausal women aged 39-60 years. Patients were randomized to receive one of three doses of LibiGel (75µg, 150µg, or 300µg) or placebo once daily for three months. The results from this trial demonstrated that patients treated with LibiGel 300µg achieved a statistically significant increase ($p<0.0001$) in the number of satisfactory sexual events (SSEs) per month compared to baseline. Treatment with LibiGel resulted in an increase from approximately 2.5 events per month at baseline to five SSEs in the final four week treatment period, representing a 238% increase. Furthermore, the increase over baseline was significantly greater ($p<0.05$) with LibiGel than in patients treated with placebo, who achieved an average increase of 1.6 SSEs over baseline.

FIGURE 6: LibiGel Phase II Results



Source: Company reports

Phase III development program

The LibiGel Phase III program consists of two six-month efficacy trials and a longer-term safety trial in patients at high risk of cardiovascular events. The FDA has never approved a therapeutic for HSDD and in addition determined that it was necessary to evaluate the longer-term safety profile of testosterone in women following the negative implications of the Women's Health Initiative (WHI) on hormone (estrogen and progestin) replacement therapy in postmenopausal women. Following an in depth negotiation with the FDA, BioSante has clarity on the requirements for NDA submission for this indication and has been granted three Special Protocol Agreements (SPAs) by the FDA for this program covering the Phase III safety and efficacy trials, treatment of HSDD, and stability studies. We believe the SPAs confirm that there is agreement with the FDA on the design of the trials, including the endpoints and sample sizes, as well as the planned statistical analysis. The company is currently conducting three Phase III trials, including two efficacy trials and a long-term safety trial. In order to submit the NDA, the FDA agreed that at least one year of exposure to LibiGel is required for women in the safety trial. This trial will then continue post-approval to assess a total treatment period of five years.

Efficacy trials

The two efficacy trials are double-blind, placebo-controlled studies designed to confirm the efficacy of LibiGel in surgically postmenopausal women. Each trial is expected to enroll approximately 500 surgically menopausal women who will be randomized to receive LibiGel (300µg) or placebo once-daily for a six month treatment period. The co-primary endpoints of the trials are the increase in the number of SSEs averaged over the final four weeks of treatment, compared to baseline, and the mean change in desire. A key secondary endpoint is decrease in distress associated with low desire. The endpoints are measured using a patient diary, which is completed daily and submitted on a weekly basis. The efficacy trials are currently ongoing and results are anticipated in 4Q11.

Safety trial

The safety study is being conducted to assess the longer-term risk of cardiovascular events and breast cancer in patients treated with LibiGel compared to placebo. The trial is designed to enroll between 2,400 and 3,100 postmenopausal women at high risk for a cardiovascular event to be treated for an initial period of 12 months, with a follow up period of four years. The primary endpoint is a composite of cardiovascular events including cardiovascular death, non fatal myocardial infarction and stroke, hospitalized unstable angina, and coronary revascularization. The incidence of breast cancer will also be assessed throughout the study. In contrast to the efficacy trials, the safety trial can enroll both surgically and naturally menopausal women.

The FDA has required that BioSante statistically rule out a two-fold increase in the risk of cardiovascular events as determined by the upper bound of the 95% confidence interval of a two sided test. An independent data monitoring committee (DMC) is scheduled to perform unblinded interim safety assessments throughout the initial phase of the trial, although treating physicians and BioSante remain blinded, and at a predetermined statistical milestone will determine when to stop enrollment. This will occur when the DMC has projected a greater than 90% probability that a statistical outcome can be met. We anticipate that enrollment can be completed at the latest by the end of 3Q11; however, we believe it is possible for the DMA to stop enrollment before this point. Importantly, while the trial will

evaluate LibiGel for a total treatment period of five years, the company is able to submit the NDA when a minimum average of one year's treatment duration has been achieved following the completion of enrollment. Therefore, we believe that the soonest the company could unblind the trial and finalize the NDA package is approximately six months following the completion of enrollment. At this time, we believe that the average duration of therapy would satisfy the FDA's request for 12 months of therapy. More conservatively, it is possible for the company to wait for the last patient enrolled to reach 12 months treatment duration prior to breaking the trial's blinding and submitting the NDA.

Interim safety analyses
To date, approximately 2,800 women have been enrolled in the trial and the average duration of therapy exceeds 12 months. Five unblinded interim safety analyses of this trial have been completed by the DMC. In October 2009, the company announced that the DMC had completed its first unblinded review of the trial. Based on this review, the DMC unanimously recommended that the trial be continued with no changes to the protocol. In this analysis, one myocardial infarction and three breast cancers were reported with no deaths. In February and June 2010, the DMC completed its second and third reviews, both times unanimously recommending that the trial be continued with no changes to the protocol. In the second analysis, a total of six adjudicated cardiovascular events and four breast cancers were reported with no deaths. In the third analysis, seven adjudicated cardiovascular events and four breast cancers were reported with no deaths. As per the fourth interim analysis, conducted in October 2010, a total of 14 cardiovascular events had been adjudicated and eight cases of breast cancer reported.

Results from the fifth DMC review were presented at the Annual Meeting of The International Society for the Study of Women's Sexual Health Meeting (ISSWSH) in February 2011. As of January 26, 2011, more than 2,800 women had been enrolled in the trial, representing over 2,900 women years of exposure to LibiGel. The median duration of exposure at this time was 12.5 months and more than 1,000 women had been on drug for at least one year. At this interim analysis, the DMC adjudicated a total of 17 cardiovascular events and eight breast cancers.

REGULATORY PRECEDENT

Although there has never been a treatment approved for HSDD, attention on the medical need has grown consistently since the approval of oral therapies to treat male erectile dysfunction and guidelines for the development of therapies for women have matured, both within the physician and regulatory communities. The FDA released guidelines on the development of therapies for HSDD in 2000; however, based on the subsequent concerns raised by the WHI results, we believe the most relevant precedents for the current regulatory environment are the FDA advisory committee meetings for Proctor and Gamble's (P&G's) Intrinsa (testosterone transdermal patch) in December 2004 and more recently for Boehringer Ingelheim's flibanserin in June 2010.

The first example, and in our view most relevant to LibiGel, is Intrinsa, a testosterone patch system that was submitted to the FDA for approval and reviewed by an Advisory Committee in December 2004. The outcome of this panel, and the eventual approval decision, was not favorable due to a requirement for longer term safety data. However, positively we believe, this panel voted strongly in support of the efficacy of testosterone in this indication and highlighted the need for therapies to treat this condition.

Flibanserin, a novel serotonin receptor modulator (5-HT_{1A} agonist/5-$HT2_A$ antagonist) that increases dopamine and norepinephrine and decreases serotonin, was developed by Boehringer Ingelheim originally as a treatment for major depression and then HSDD. In June 2010, an FDA advisory panel voted against recommending approval of the drug. In addition to primary concerns over the drug's lack of efficacy (it failed to meet the co-primary endpoint of improving desire), multiple target specific safety concerns were raised by the FDA and the advisory committee, including syncope, accidental injury, and depression and suicidality. However, similar to the Intrinsa panel, the flibanserin panel was strongly supportive of the need for therapies to treat HSDD.

Although the flibanserin Advisory Committee meeting likely has limited read through to LibiGel, it did re-affirm that the endpoints being used in the LibiGel Phase III trials are those preferred by the FDA. In addition, we view it as important to note that during this panel, the FDA made specific reference to the usefulness of responder rates in interpreting the clinical significance of an HSDD drug, commenting that the agency would look favorably on statistical demonstration of more responders on drug than on placebo. We believe that these data will be useful in interpreting the successful outcome of the LibiGel efficacy trials.

Intrinsa

Intrinsa is a transdermal testosterone patch that was being developed by P&G for HSDD. Similar to the LibiGel program, Intrinsa was being developed for post-menopausal women; however, the Phase III program assessed both surgically and naturally menopausal women. The Phase III program was successfully completed with both primary and key secondary efficacy endpoints met and no overtly concerning safety signals. However, following a negative FDA Advisory Committee meeting in December 2004, the Intrinsa program was suspended, and no progress has been reported since that time. The two primary points of debate for the Advisory Committee were the relevance of the clinical benefit of Intrinsa and the need for longer term safety data specifically related to cardiovascular risk. Relating to efficacy, the FDA asked the panel to discuss whether the benefit of the drug was not only statistically significant but clinically meaningful. While the FDA and Advisory Committee members recognized the efficacy and clinical benefit of Intrinsa, it saw a need for longer term safety data to rule out the risk of serious adverse effects that could not be assessed based on the available clinical program, namely cardiovascular and breast cancer risk. As discussed previously, these concerns, although not compellingly data driven, are known hypothetical risks with testosterone therapy.

The Intrinsa Phase III program in surgically menopausal women included two trials, SM1 and SM2, enrolling a total of 1,095 women. The primary efficacy endpoint was the number of satisfying sexual events at the end of a six month treatment period and key secondary endpoints included improvements in desire and distress. All women in these trials were on stable doses of estrogen and were in stable relationships. Treatment with Intrinsa demonstrated an average treatment difference of one satisfactory sexual event (SSEs) per month, a statistically significant result ($p \leq 0.001$). As summarized in Figure 7, the change from baseline in SSEs on Intrinsa was 2.1 and 1.6 in the first and second trials, compared to 1.0 and 0.7 on placebo. In addition, there were significantly more responders on testosterone than on placebo, with a difference in percent of responders of 14% ($p \leq 0.0002$). Statistically significant increases in desire were observed compared to placebo in both trials ($p=0.0006$) as well as decreases in distress in excess of placebo changes ($p \leq 0.01$).

During the Advisory Committee meeting, the FDA stated that it agreed that the primary statistical endpoints had been met and the panel voted 14-3 supporting that the efficacy benefit provided by Intrinsa was clinically meaningful.

FIGURE 7: Intrinsa Phase III Results

Efficacy	SM 1		SM 2	
	Placebo	Intrinsa	Placebo	Intrinsa
Patient numbers	279	283	266	267
Duration of therapy	6 months		6 months	
SSEs				
Baseline	2.9	2.8	3.2	3.0
Change	1.0	2.1	0.7	1.6
Pbo subtracted change		**1.1**		**0.9**
Personal distress score				
Baseline	62.6	64.8	66.4	66.6
Change	-16.3	-23.6	-18.3	-24.3
Pbo subtracted change		**-7.3**		**-6.0**
Sexual desire score				
Baseline	20.8	19.8	23.4	21.7
Change	6.9	11.9	6.2	11.4
Pbo subtracted change		**5.0**		**5.2**

Source: Company reports

The safety profile generated by the Intrinsa Phase III program, in our view, is the most substantive database of the use of low dose testosterone in women with sexual dysfunction. Data were presented at the 2004 Advisory Committee meeting to address all relevant questions concerning the use of androgens in woman, as discussed previously. The FDA characterized the potential risks as "likely" (androgenic adverse effects), "possible" (impact on cardiovascular risk factors), and "speculative" (increased cardiovascular morbidity and risk of breast cancer). While the Intrinsa trials did not provide evidence of an overt signal of risk, both the FDA and Advisory Committee believed that the sample size and duration of treatment were inadequate to exclude serious risks of cardiovascular disease and breast cancer.

FIGURE 8: Androgenic Adverse Effects with Intrinsa

Androgenic effects	SM 1		SM 2	
	Placebo	Intrinsa	Placebo	Intrinsa
Clinical assessments				
Acne	1.9%	2.7%	1.3%	2.5%
Increase in baseline of 1-2				
Facial Hair				
Chin: Increase in baseline of 1-2	4.2%	4.2%	4.2%	7.0%
Upper lip: Increase in baseline of 1-2	6.1%	5.7%	5.0%	5.3%
Adverse events				
Acne	6.1%	6.0%	4.1%	7.5%
Hirsutism	6.5%	5.7%	5.3%	9.0%
Alopecia	3.2%	3.2%	2.6%	5.3%
Voice deepening	2.9%	2.5%	1.5%	3.0%
Clitoromegaly	0.0%	0.0%	0.0%	0.4%

Source: FDA

Androgenic effects

The frequency of androgenic adverse events in the Intrinsa Phase III program, shown in Figure 8, was greater on drug (17.7%) than in the placebo group (14.4%). In our view, the androgenic effects of Intrinsa were not concerning, with 94% of events reported to be mild in nature. In addition, a large majority of patients (78%) who did experience an androgenic effect did not report the occurrence of multiple events, although Intrinsa patients were more likely to experience multiple events than those on placebo.

Impact on markers of cardiovascular risk

As summarized in Figure 9, the data from the Intrinsa trials do not demonstrate an overt signal of risk based on assessment of known markers of cardiovascular risk. Changes from baseline in lipid profile during the double blind phase were small and, as stated by the FDA, "not likely to be of clinical significance". There were no discernable differences in carbohydrate metabolism. There were no clinically relevant changes in systolic or diastolic blood pressure. There was a small increase in weight from baseline in patients treated with Intrinsa compared to placebo patients who showed a weight neutral or slight weight loss outcome.

FIGURE 9: Effects on Cardiovascular Risk Markers

Cardiovascular risk factors	SM 1		SM 2	
(Change from baseline)	Placebo	Intrinsa	Placebo	Intrinsa
Weight (kg)	-0.24	0.18	-0.19	0.3
HbA1c (%)	0.03	0.02	0.02	0.05
Blood pressure (mmHg)				
Systolic	-0.2	0.2	-0.9	0.1
Diastolic	-1.2	-0.1	-0.3	0.1
Cholesterol (mg/dL)				
Total	-2.9	-2.8	-1.9	-3.6
LDL	-2.7	-0.1	-2.1	-2.3
HDL	1.6	0.4	1.2	0.8
Triglycerides	-9	-17	-9	-13

Source: FDA

Although mean changes in these cardiovascular risk markers showed no concerning signals over the initial six month treatment period, the FDA did highlight potentially confounding data from the longer term, open-label extension periods. As shown in Figure 10, the proportion of patients with high LDL cholesterol levels (LDL > 160mg/dL) increased with time relative to placebo. However, it was also noted that HDL cholesterol levels did not demonstrate any concerning signal over time. In addition, while mean glucose levels did not increase over the initial six month treatment phase, the change from baseline appeared to increase with prolonged duration of Intrinsa treatment.

FIGURE 10: Longer-Term Impacts with Intrinsa

	Placebo	Intrinsa		
		Up to 6 mos	6-12 mos	12-18 mos
LDL >160mg/dL	1.5%	1.7%	2.2%	2.3%
SBP increase				
10-19mmHg	17.2%	16.9%	22.1%	19.5%
20-29mmHg	5.3%	5.8%	5.2%	7.0%
Weight change ≥7&				
Gain	2.2%	4.4%	9.0%	9.1%
Loss	3.1%	4.4%	8.5%	9.1%

Source: FDA

The limitation of these analyses is demonstrated by the data for weight change. As noted previously for the six month treatment period, there was a slight increase in weight in patients treated with Intrinsa and this change appeared to continue to increase over time. However, the same trend is observed with weight loss (a cardiovascular benefit) with an increasing magnitude of effect over time with Intrinsa. Overall, the FDA was not concerned by the magnitude of the changes observed but questioned the potential risks with longer term therapy in at risk populations (e.g., diabetics, hypertensive patients). This view reiterated the FDA's position that there was limited data indicating a risk with testosterone but the available database at the Intrinsa panel was insufficient to rule out unacceptable risk.

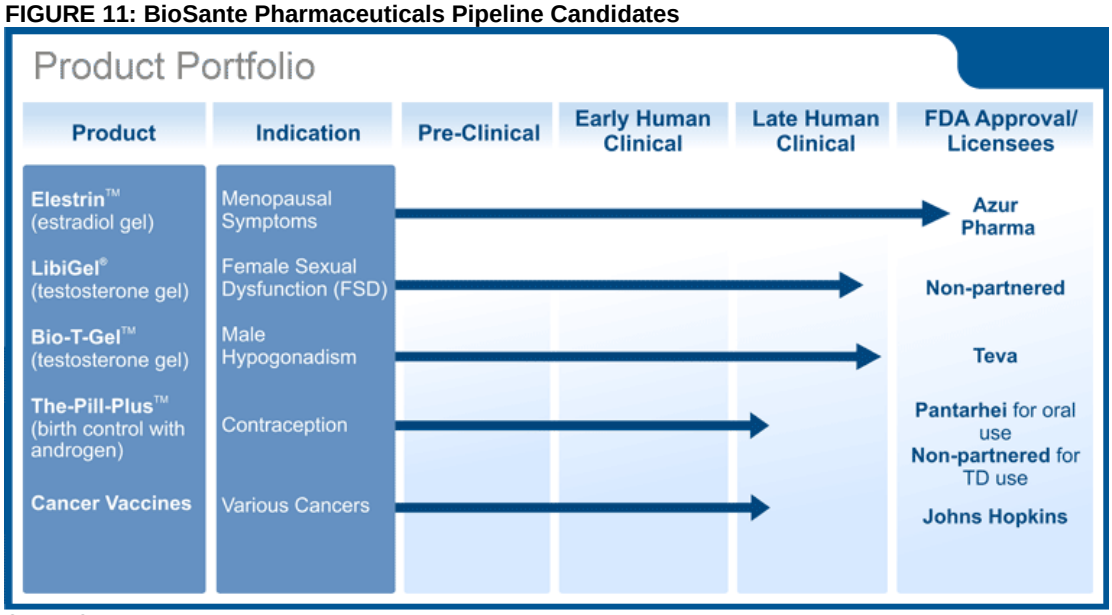
Speculative risks

There were no data in the Intrinsa program to suggest increased cardiovascular morbidity, and we specifically note that no myocardial infarctions were reported. There were four reported cased of breast cancer in the Intrinsa clinical program, one on placebo and three on drug. Only one of this cases involved hormone receptor positive breast cancer in a patient treated with Intrinsa. These data obviously, in our view, do not suggest an increased risk; however, the limited long term patient exposure and concomitant exposure to estrogen was again highlighted by the FDA as a concerning unknown. The Advisory Committee ultimately agreed with the FDA that longer term data were needed to rule out unacceptable risks.

PIPELINE PROGRAMS

BioSante's development pipeline contains additional hormone products that have been out licensed to development partners and a portfolio of cancer vaccines acquired through the 2009 merger with Cell Genesys. In addition, the company's proprietary calcium phosphate (CaP) technology has yielded multiple pre-clinical candidates focused on aesthetic medicine and vaccines. This technology is based on the use of small, solid, uniform particles, intended to increase the stability of drugs and act as systems to deliver drugs into the body. The most advanced program, which has successfully completed a Phase I safety trial, is in aesthetic medicine where the company believes the technology can serve as a facial line filler. We currently assign no value to BioSante's pipeline programs or its technology platform but do note the opportunity for value generation through current and potential development partnerships.

FIGURE 11: BioSante Pharmaceuticals Pipeline Candidates



Source: Company reports

The Pill-Plus

The Pill-Plus is an oral contraceptive that adds an androgen, similar to testosterone, to the typical contraceptive combination of estrogen and progestin. It is hypothesized that addition of the androgen component can offset any decrease in sexual desire, sexual activity, and mood changes. Results from a randomized Phase II trial in 82 women demonstrated an increase in the frequency of sexual activity ($p< 0.05$) and reduced frequency of rejection of initiation of sexual activity by partner ($p< 0.05$). In May 2007, BioSante out licensed U.S. rights to The Pill-Plus to Pantarhei Bioscience B.V., which is responsible for all costs of development and commercialization of the product. BioSante is entitled to receive development and regulatory milestones as well as royalties on future product sales. If the product is sublicensed by Pantarhei, which we expect to occur, BioSante is entitled to receive a percentage of all payments received by Pantarhei.

GVAX cancer immunotherapies

BioSante acquired the rights to the GVAX program through its merger with Cell Genesys in October 2009. BioSante has committed to dedicating minimal resources to the GVAX program without external funding support; however, multiple investigator-sponsored Phase II trials are ongoing in leukemia and pancreatic and breast cancers. The studies are being conducted at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. Orphan drug designation has been received for GVAX candidates being developed to the treat pancreatic cancer, acute myeloid leukemia, and chronic myeloid leukemia and melanoma.

Cancer immunotherapies are vaccines designed to stimulate the patient’s immune system to effectively fight cancer. GVAX cancer immunotherapies comprise tumor cells that are genetically modified to secrete an immune-stimulating cytokine, granulocyte-macrophage colony-stimulating factor, or GM-CSF. These vaccines consist of whole tumor cells, which have been exposed to radiation to ensure their safety, designed to activate the immune system against multiple tumor cell components.

Cell Genesys had previously been conducting a Phase III trial (VITAL-2) for a GVAX vaccine in patients with prostate cancer. However, in 2008, this trial was halted at the recommendation of an independent data monitoring committee based on an imbalance of deaths in patients receiving the vaccine compared with those in the control arm. The trial enrolled 408 patients, and, of the 114 deaths recorded, 67 were in patients treated with the vaccine. More positively, BioSante announced in May 2010 that development of GVAX prostate program had been reinitiated based on further data and increased knowledge from the VITAL-2 trial.

MANAGEMENT

Stephen M. Simes
President & Chief Executive Officer
Mr. Simes has served as BioSante's Vice Chairman, President, and CEO since 1998. Prior to joining the company, Mr. Simes was President and CEO Unimed Pharmaceuticals, Inc., now a wholly owned subsidiary of Abbott Laboratories, from 1994 to 1997. Mr. Simes was Chairman, President, and CEO of Gynex Pharmaceuticals, Inc., a company that concentrated on the AIDS, endocrinology, urology, and growth disorders, from 1989 to 1993, when the company was acquired by Savient Pharmaceuticals Inc. In addition, Mr. Simes currently serves on the board of directors of Ceregene, Inc., a privately held biotechnology company focused on the treatment of major neurodegenerative disorders using the delivery of nervous system growth factors.

Phillip B. Donenberg, CPA
Senior Vice President of Finance, Chief Financial Officer, and Secretary
Mr. Donenberg has served as BioSante's CFO, Treasurer, and Secretary since 1998. Before joining BioSante, Mr. Donenberg was Controller of Unimed Pharmaceuticals, Inc., now a wholly owned subsidiary of Abbott Laboratories, from 1995 to 1998, and previously he has held similar positions at pharmaceutical companies including Gynex Pharmaceuticals, Inc. (acquired by Savient Pharmaceuticals, Inc.), Applied NeuroSolutions, Inc., and Xtramedics, Inc.

Michael C. Snabes, M.D., Ph.D.
Senior Vice President, Medical Affairs
Dr. Snabes joined BioSante in 2008 as VP of Clinical Development and, prior to joining the company, had acted as a medical consultant to BioSante since 2005. Before joining BioSante, Dr. Snabes was an Associate Professor in the Section of Reproductive Endocrinology and Infertility in the Department of Obstetrics and Gynecology at The University of Chicago Pritzker School of Medicine. Previously, from 1999 to 2004, Dr. Snabes served as Medical Advisor in Clinical Research and Development in Inflammation, Arthritis, and Pain at Pharmacia, Inc. and Pfizer, Inc. Dr. Snabes is a board certified reproductive endocrinologist and holds a Ph.D. in physiology and reproductive endocrinology. He is an elected Fellow of the American College of Obstetrics and Gynecology, the American College of Surgeons, and the American College of Endocrinology and has authored more than 135 publications and abstracts.

Joanne Zborowski
Vice President, Clinical Development
Ms. Zborowski joined BioSante in 2002 and has served as VP of Clinical Development since September 2010. Previously, from 2007 to 2010, Ms. Zborowski served as Director of Clinical Development. Prior to joining BioSante, Ms. Zborowski held positions in Medical Affairs and the Pharmaceutical Products Division at Abbott Laboratories from 1990 to 1998 and held similar consulting positions from 1999-2002.

Jeffrey W. Winkelman, Ph.D., J.D.
Vice President, Oncology Programs
Dr. Winkelman joined BioSante in January 2010 as Vice President, Oncology Programs, and has acted as a consultant to the company since October 2009. From December 2004 until October 2008, Dr. Winkelman was the Vice President, Intellectual Property at Cell Genesys, Inc, which was acquired by BioSante. Previously, from 1994 until 2004, Dr. Winkelman held similar positions with other biotechnology companies, including Sibia Neurosciences, Inc., Advanced Tissue Sciences, Inc., and Elitra Pharmaceuticals. Dr. Winkelman was also an associate at the IP law firm of Brown, Martin, Haller & McClain.

William D. Milling, CPA
Vice President, Operations
Mr. Milling served as BioSante's Controller and Senior Director of Operations since 2004. Previously, Mr. Milling was Controller of Dor BioPharma from 2002 to 2004 and, from 1994 to 2002, held various financial and systems positions of increasing responsibility with CCH, Inc.

FIGURE 12: LibiGel US Revenue Model

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Total US population	313,232,044	316,265,537	319,330,342	322,422,965	325,539,790	328,677,531	331,833,494	335,005,223	338,190,395	341,386,665	344,591,727	347,803,053
Female	158,967,429	160,476,639	162,005,574	163,552,634	165,116,007	166,694,120	168,285,614	169,889,283	171,503,898	173,128,221	174,761,020	176,400,878
Oophorectomy prevalence												
Average (25-74 yrs)	11.0%	11.1%	11.1%	11.2%	11.2%	11.3%	11.3%	11.3%	11.3%	11.3%	11.4%	11.4%
Surgically menopausal women (prevalence)												
Total (25-74 yrs)	10,533,718	10,706,919	10,874,046	11,044,067	11,222,588	11,389,205	11,526,362	11,644,350	11,763,521	11,886,383	11,990,041	12,046,360
HSDD prevalance												
Surgically menopausal women	7.4%	7.4%	7.4%	7.4%	7.4%	7.4%	7.4%	7.4%	7.4%	7.4%	7.4%	7.4%
Naturally menopausal women	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%
Women with HSDD	2,971,390	3,056,212	3,140,455	3,223,227	3,308,884	3,388,855	3,459,002	3,520,427	3,582,566	3,641,991	3,685,768	3,704,717
Surgically menopausal	779,495	792,312	804,679	817,261	830,471	842,801	852,951	861,682	870,501	879,592	887,263	891,431
Naturally menopausal (55-74 yrs)	2,191,895	2,263,900	2,335,776	2,405,966	2,478,413	2,546,054	2,606,052	2,658,746	2,712,066	2,762,399	2,798,505	2,813,286
LibiGel - Worst Case Scenario												
Penetration												
Surgically menopausal			*2%*	*4%*	*9%*	*11%*	*12%*	*13%*	*14%*	*14%*	*14%*	*14%*
Naturally menopausal (55-74 yrs)			*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Patients on therapy			12,070	28,604	74,742	92,708	102,354	112,019	121,870	123,143	124,217	124,800
Surgically menopausal			12,070	28,604	74,742	92,708	102,354	112,019	121,870	123,143	124,217	124,800
Naturally menopausal (55-74 yrs)			0	0	0	0	0	0	0	0	0	0
Avg Rx/year			10	10	10	10	10	10	10	10	10	6
Total Rx/year			120,702	286,041	747,424	927,081	1,023,541	1,120,186	1,218,701	1,231,429	1,242,168	748,802
Cost per Rx			$240	$240	$245	$250	$255	$260	$265	$270	$276	$281
Sales ($MM)			**29.0**	**68.6**	**183.0**	**231.5**	**260.7**	**291.0**	**322.9**	**332.8**	**342.4**	**210.6**
LibiGel - Base Case Scenario												
Penetration												
Surgically menopausal			*2%*	*4%*	*9%*	*11%*	*12%*	*13%*	*14%*	*14%*	*14%*	*14%*
Naturally menopausal (55-74 yrs)			*0.5%*	*1.0%*	*2.0%*	*3.0%*	*3.5%*	*3.8%*	*4.0%*	*4.0%*	*4.0%*	*4.0%*
Patients on therapy			23,749	52,664	124,311	169,090	193,566	211,722	230,353	233,639	236,157	237,332
Surgically menopausal			12,070	28,604	74,742	92,708	102,354	112,019	121,870	123,143	124,217	124,800
Naturally menopausal (55-74 yrs)			11,679	24,060	49,568	76,382	91,212	99,703	108,483	110,496	111,940	112,531
Avg Rx/year			10	10	10	10	10	10	10	10	10	6
Total Rx/year			237,491	526,638	1,243,107	1,690,897	1,935,659	2,117,216	2,303,527	2,336,389	2,361,570	1,423,990
Cost per Rx			$240	$240	$245	$250	$255	$260	$265	$270	$276	$281
Sales ($MM)			**57.0**	**126.4**	**304.3**	**422.2**	**493.0**	**550.0**	**610.4**	**631.5**	**651.0**	**400.4**
LibiGel - Best Case Scenario												
Penetration												
Surgically menopausal			*2%*	*4%*	*9%*	*11%*	*12%*	*13%*	*14%*	*14%*	*14%*	*14%*
Naturally menopausal (55-74 yrs)			*0.5%*	*1.0%*	*2.0%*	*4%*	*7%*	*8%*	*9%*	*10%*	*10%*	*10%*
Patients on therapy			23,749	52,664	124,311	194,550	284,778	324,718	365,956	385,571	404,067	406,129
Surgically menopausal			12,070	28,604	74,742	92,708	102,354	112,019	121,870	123,143	124,217	124,800
Naturally menopausal (55-74 yrs)			11,679	24,060	49,568	101,842	182,424	212,700	244,086	262,428	279,851	281,329
Avg Rx/year			10	10	10	10	10	10	10	10	10	6
Total Rx/year			237,491	526,638	1,243,107	1,945,503	2,847,777	3,247,183	3,659,560	3,855,708	4,040,673	2,436,773
Cost per Rx			$240	$240	$245	$250	$255	$260	$265	$270	$276	$281
Sales ($MM)			**57.0**	**126.4**	**304.3**	**485.8**	**725.3**	**843.6**	**969.7**	**1,042.1**	**1,114.0**	**685.2**

Source: JMP Securities estimates

FIGURE 13: BioSante Pharmaceuticals Earnings Model ($MMs, except per share data)

	2006	2007	2008	1Q09	2Q09	3Q09	4Q09	2009	1Q10	2Q10	3Q10	4Q10E	2010E	1Q11E	2Q11E	3Q11E	4Q11E	2011E	2012E
Revenue																			
Royalty revenues	0.0	0.1	0.0	0.0	0.1	0.0	1.1	1.1	2.2	0.0	0.1	0.0	2.3	0.0	0.0	0.0	0.0	0.0	0.0
Collaborative reveues	14.4	0.3	3.4	0.1	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Other revenues	0.1	0.2	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Revenue	**14.4**	**0.5**	**3.8**	**0.1**	**0.1**	**0.0**	**1.1**	**1.3**	**2.3**	**0.0**	**0.1**	**0.0**	**2.3**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	**14.4**	**0.5**	**3.8**	**0.1**	**0.1**	**0.0**	**1.1**	**1.3**	**2.3**	**0.0**	**0.1**	**0.0**	**2.3**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Operating Expenses																			
R&D	3.9	4.8	15.8	3.1	3.5	3.4	3.7	13.7	9.4	8.7	9.7	9.0	36.8	10.1	11.1	11.5	10.3	43.0	34.4
SG&A	4.5	4.3	5.1	1.0	1.2	1.5	1.6	5.4	1.5	1.5	1.5	1.5	6.1	1.6	1.6	1.7	1.7	6.7	7.3
Acquisition related charges	0.0	0.0	0.0	0.0	0.0	1.5	27.7	29.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Licensing expense	3.5	0.0	0.8	0.0	0.0	0.0	0.3	0.3	0.3	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.0
Depreciation and amortization	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.2	0.2
Total Operating Expenses	**12.1**	**9.2**	**21.8**	**4.1**	**4.7**	**6.4**	**33.4**	**48.7**	**11.2**	**10.2**	**11.3**	**10.6**	**43.3**	**11.7**	**12.8**	**13.2**	**12.1**	**49.8**	**41.9**
Operating Income (Loss)	**2.4**	**(8.7)**	**(18.0)**	**(4.1)**	**(4.6)**	**(6.4)**	**(32.4)**	**(47.4)**	**(9.0)**	**(10.2)**	**(11.2)**	**(10.6)**	**(41.0)**	**(11.7)**	**(12.8)**	**(13.2)**	**(12.1)**	**(49.8)**	**(41.9)**
Interest income	0.4	1.1	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.2	0.3	0.2	0.1	0.8	0.2
Interest expense	0.0	0.0	0.0	0.0	0.0	0.0	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.7)	(0.2)	(0.2)	(0.2)	(0.2)	(0.7)	(0.7)
Other income (expense)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(1.4)	(0.4)	(0.2)	0.0	(2.0)	0.0	0.0	0.0	0.0	0.0	0.0
Total other income (expense)	**0.4**	**1.1**	**0.6**	**0.0**	**0.0**	**0.0**	**(0.1)**	**(0.1)**	**(1.6)**	**(0.6)**	**(0.3)**	**0.0**	**(2.5)**	**0.0**	**0.1**	**0.0**	**(0.0)**	**0.2**	**(0.4)**
Net Income Before Taxes	2.8	(7.6)	(17.4)	(4.1)	(4.6)	(6.4)	(32.5)	(47.5)	(10.5)	(10.8)	(11.6)	(10.6)	(43.5)	(11.7)	(12.7)	(13.1)	(12.1)	(49.7)	(42.3)
Provision (benefit) for income taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tax rate												0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	*0.0%*
Net Income (Loss)	**2.8**	**(7.6)**	**(17.4)**	**(4.1)**	**(4.6)**	**(6.4)**	**(32.5)**	**(47.5)**	**(10.5)**	**(10.8)**	**(11.6)**	**(10.6)**	**(43.5)**	**(11.7)**	**(12.7)**	**(13.1)**	**(12.1)**	**(49.7)**	**(42.3)**
EPS																			
Basic	$0.13	($0.30)	($0.64)	($0.15)	($0.17)	($0.21)	($0.87)	($1.40)	($0.19)	($0.17)	($0.16)	($0.13)	($0.65)	($0.13)	($0.14)	($0.14)	($0.12)	($0.52)	($0.40)
Diluted	$0.13	($0.30)	($0.64)	($0.15)	($0.17)	($0.21)	($0.87)	($1.40)	($0.19)	($0.17)	($0.16)	($0.13)	($0.65)	($0.13)	($0.14)	($0.14)	($0.12)	($0.52)	($0.40)
Weighted shares outstanding																			
Basic	21.2	25.5	27.3	27.4	27.4	30.4	50.4	34.0	56.3	64.6	71.2	81.9	68.5	91.8	93.7	93.9	101.1	95.1	105.0
% growth		*20.3%*	*7.1%*		*0.0%*	*10.9%*	*65.5%*	*24.3%*	*11.8%*	*14.7%*	*10.2%*	*0.2%*	*101.8%*	*0.2%*	*2.0%*	*0.2%*	*0.2%*	*38.8%*	*2.0%*
Diluted	21.5	25.5	27.3	27.4	27.4	30.4	50.4	34.0	56.3	64.6	71.2	81.9	68.5	91.8	93.7	93.9	101.1	95.1	105.0
% growth		*18.6%*	*7.1%*		*0.0%*	*10.9%*	*65.5%*	*24.3%*	*11.8%*	*14.7%*	*10.2%*	*0.2%*	*101.8%*	*0.2%*	*2.0%*	*0.2%*	*0.2%*	*38.8%*	*2.0%*
Cash Flow																			
GAAP Net Income	2.8	(7.6)	(17.4)	(4.1)	(4.6)	(6.4)	(32.5)	(47.5)	(10.5)	(10.8)	(11.6)	(10.6)	(43.5)	(11.7)	(12.7)	(13.1)	(12.1)	(49.7)	(42.3)
Depreciation and amortization	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.2	0.2
Stock Based Compensation	1.1	0.7	1.1	0.3	0.3	0.3	0.3	1.3	0.2	0.3	0.3	0.3	1.0	0.3	0.3	0.3	0.3	1.1	1.1
Other adjustments	(9.0)	7.5	0.7	(0.8)	0.2	2.3	26.0	27.7	4.1	1.6	0.4	0.0	6.1	0.0	0.0	0.0	0.0	0.0	0.0
Operating Burn	**(5.0)**	**0.7**	**(15.5)**	**(4.5)**	**(4.1)**	**(3.7)**	**(6.1)**	**(18.4)**	**(6.2)**	**(8.9)**	**(10.9)**	**(10.3)**	**(36.2)**	**(11.4)**	**(12.4)**	**(12.8)**	**(11.8)**	**(48.4)**	**(41.1)**
Cash at start of period	0.3	7.7	15.6	11.8	10.2	6.0	13.2	11.8	29.9	41.2	46.4	35.5	29.9	42.3	54.8	42.4	29.5	42.3	44.1
Cash from operations	(5.0)	0.7	(15.5)	(4.5)	(4.1)	(3.7)	(6.1)	(18.4)	(6.2)	(8.9)	(10.9)	(10.3)	(36.2)	(11.4)	(12.4)	(12.8)	(11.8)	(48.4)	(41.1)
Cash from investing	5.0	(11.2)	11.3	2.9	0.0	(0.0)	(0.0)	2.9	(0.0)	(0.0)	0.0	0.0	(0.0)					0.0	
Cash from financing	7.4	18.5	0.3	(0.0)	(0.1)	10.9	22.8	33.7	17.5	14.1	0.0	17.0	48.6	23.9	0.0	0.0	26.3	50.2	45.1
Shares issued												10.6		12.2			7.0	19.2	8.0
Price per share												1.71		2.06			4.00	0.0	6.0
Effect of Fx	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0					0.0	
Cash at end of period	**7.7**	**15.6**	**11.8**	**10.2**	**6.0**	**13.2**	**29.9**	**29.9**	**41.2**	**46.4**	**35.5**	**42.3**	**42.3**	**54.8**	**42.4**	**29.5**	**44.1**	**44.1**	**48.1**

Source: Company reports and JMP Securities estimates

JMP FACTS AND DISCLOSURES

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Market Perform	Hold	119	*37%*	Hold	119	*37%*	9	*8%*
Market Underperform	Sell	4	*1%*	Sell	4	*1%*	0	*0%*
TOTAL:		319	*100%*		319	*100%*	50	*16%*

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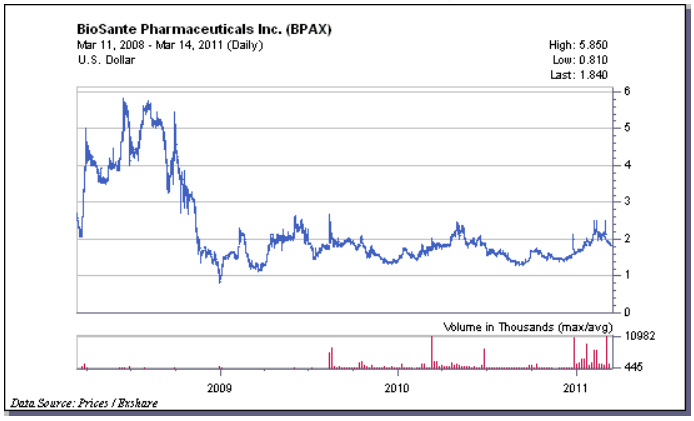
Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. If the latest date is different than the report date, then the price is as of the previous day's close. The action reflected in this note is not annotated in the stock price chart. Source: FactSet and JMP Securities.



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JMP SECURITIES LLC

600 Montgomery Street, Suite 1100, San Francisco, CA 94111-2713, www.jmpsecurities.com

James F. Wilson, CFA
Director of Equity Research
(415) 835-8975

Business Services

Business & Professional Services
Kevane A. Wong (415) 835-8976

Financial Processing & Outsourcing
David M. Scharf (415) 835-8942
Kevane A. Wong (415) 835-8976

Consumer

Hardline Retail
Peter J. Keith (212) 906-3544
Aaron Mo (212) 906-3547

Financial Services

Capital Markets
David Trone (212) 906-3525
Steven Fu, CFA (212) 906-3548

Commercial Banks, Consumer & Specialty Finance
John Hecht (415) 835-3912
Kyle M. Joseph (415) 835-3940

Insurance
Matthew J. Carletti (312) 768-1784

Market Structure
David M. Scharf (415) 835-8942
Kevane A. Wong (415) 835-8976

Residential & Commercial Real Estate Finance
Steven C. DeLaney (404) 848-7773
Trevor Cranston, CFA (415) 869-4431

Trevor Cranston, CFA (415) 869-4431

Healthcare

Biotechnology
Charles C. Duncan, PhD (212) 906-3510
Jason N. Butler, PhD (212) 906-3505

Liisa A. Bayko (312) 768-1785

Jason N. Butler, PhD (212) 906-3505

China Healthcare Facilities & Services
Peter L. Martin, CFA (415) 835-8904
Andy Wu (415) 835-3939

Healthcare Facilities & Services
Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963

Healthcare Services
Constantine Davides, CFA (617) 235-8502
Tim McDonough (617) 235-8504

Medical Devices
Jose Haresco, PhD (415) 869-4477

Real Estate

Hotels & Resorts
William C. Marks (415) 835-8944

Housing & Housing Supply Chain
Michael G. Smith (415) 835-8965

James F. Wilson, CFA (415) 835-8975

Land Development
James F. Wilson, CFA (415) 835-8975

Michael G. Smith (415) 835-8965

Real Estate & Property Services
William C. Marks (415) 835-8944

Real Estate & Real Estate Technology
James F. Wilson, CFA (415) 835-8975

Michael G. Smith (415) 835-8965

REITs: Healthcare
Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963

REITs: Office & Industrial
Mitch Germain (212) 906-3546

REITs: Residential
James F. Wilson, CFA (415) 835-8975

Michael G. Smith (415) 835-8965

Technology

Clean Technology
Alex Gauna (415) 835-8998

Bryce Dille, CFA (415) 835-8916

Communications Equipment
Douglas Ireland (415) 835-3918

IT Hardware
Douglas Ireland (415) 835-3918

Semiconductors
Alex Gauna (415) 835-8998
Matt Danziger (415) 869-4454

Software
Patrick Walravens (415) 835-8943
Greg McDowell (415) 835-3934

Greg McDowell (415) 835-3934

For Additional Information

Mark Lehmann
Director of Equities
(415) 835-3908

Erin Seidemann
Vice President, Publishing
(415) 835-3970