BIOSANTE PHARMACEUTICALS INC
Form S-3
August 23, 2006

As filed with the Securities and Exchange Commission on August 23, 2006

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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111 Barclay Boulevard
Lincolnshire, Illinois 60069
(847) 478-0500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary
BioSante Pharmaceuticals, Inc.
111 Barclay Boulevard
Lincolnshire, Illinois 60069
(847) 478-0500
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:
Amy E. Culbert, Esq.
Oppenheimer Wolff & Donnelly LLP
45 South Seventh Street, Suite 3300
Minneapolis, Minnesota 55402
(612) 607-7287

Approximate date of commencement of proposed sale to the public:
From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or reinvestment plans, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes or securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per unit (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Common Stock, par value $0.0001 per share	5,147,520	$2.01	$10,346,515	$1,107.08

(1) The amount to be registered hereunder consists of an aggregate of 5,147,520 shares of common stock to be sold by the selling stockholders named in this registration statement. Of the shares of common stock, 3,812,978 shares are currently outstanding and 1,334,542 shares are issuable upon the exercise of warrants. In addition, pursuant to Rule 416 under the Securities Act of 1933, this registration statement includes an indeterminate number of additional shares that may be offered and sold to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, based upon the average of the high and low sale prices of the registrant's common stock on August 21, 2006, as reported by the American Stock Exchange.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated August 23, 2006

PRELIMINARY PROSPECTUS

5,147,520 Shares

Common Stock

Selling stockholders of BioSante Pharmaceuticals, Inc. are offering an aggregate of 5,147,520 shares of common stock. These shares may be offered from time to time by the selling stockholders through public or private transactions, on or off the American Stock Exchange, at prevailing market prices or at privately negotiated prices. BioSante will not receive any proceeds from the sale of shares offered by the selling stockholders.

The shares of common stock offered will be sold as described under the heading “Plan of Distribution,” beginning on page 25.

Our common stock is listed on the American Stock Exchange under the symbol “BPA.” On August 21, 2006, the last sale price of our common stock on the American Stock Exchange was $1.99 per share.

The common stock offered involves a high degree of risk. We refer you to “Risk Factors,” beginning on page 9.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2006

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In this prospectus, references to "BioSante," the "company," "we," "our" or "us," unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, BioVant™, NanoVant™, CAP-Oral™, BioAir™, Bio-EBGel®, LibiGel®, LibiGel-E/P-Gel™, LibiGel-E/T™ and Bio-T-Gel™.

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. This prospectus may only be used where it is legal to sell these securities. The information in this prospectus is accurate as of the date on the front cover. You should not assume that the information contained in this prospectus is accurate as of any other date.

This prospectus does not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus or the solicitation of a proxy, in any jurisdiction to or from any person to whom or from whom it is unlawful to make an offer, solicitation of an offer or proxy solicitation in that jurisdiction.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC for the common stock offered by the selling stockholders under this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information that is not contained in this prospectus. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

We file reports, proxy statements and other information with the Securities and Exchange Commission. Copies of our reports, proxy statements and other information may be inspected and copied at the following public reference facility maintained by the SEC:

100 F Street, N.E,
Washington, D.C. 20549

Copies of these materials also can be obtained by mail at prescribed rates from the Public Reference Section of the SEC, 100 F Street, N.E., Washington, D.C. 20549 or by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site that contains reports, proxy statements and other information regarding us. The address of the SEC web site is *http://www.sec.gov*.

Our common stock is listed on the American Stock Exchange. Reports and other information concerning BioSante may also be inspected at the offices of the American Stock Exchange, 86 Trinity Place, Seventh Floor, New York, NY 10006 or on the American Stock Exchange website at *http://www.amex.com.*

We also file annual audited and interim unaudited financial statements, proxy statements and other information with the Ontario, Alberta and British Columbia Securities Commissions. Copies of these documents that are filed through the System for Electronic Document Analysis and Retrieval “SEDAR” of the Canadian Securities Administrators are available at its web site *http://www.sedar.com*.

In addition, we maintain a web site that contains information regarding our company, including copies of reports, proxy statements and other information we file with the SEC. The address of our web site is *www.biosantepharma.com*. Our web site, and the information contained on that site, or connected to that site, are not intended to be part of this prospectus.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” into this prospectus the information contained in the documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will update and supersede this information. We are incorporating by reference the following documents into this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2005;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2006 and June 30, 2006;
- our Current Reports on Form 8-K filed on February 1, 2006, February 17, 2006, March 22, 2006, May 26, 2006, June 12, 2006, July 10, 2006 and July 24, 2006; and

- the description of our common stock contained in our registration statement on Form 8-A and any amendments or reports filed for the purpose of updating such description.

We are also incorporating by reference any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 after the date of this prospectus and prior to the termination of the offering of the securities to which this prospectus relates. In no event, however, will any of the information that we "furnish" to the SEC in any Current Report on Form 8-K or any other report or filing be incorporated by reference into, or otherwise included in, this prospectus.

You may request of copy of these filings, at no cost, by writing to Phillip B. Donenberg, Chief Financial Officer, Treasurer and Secretary, BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069, by telephone at (847) 478-0500 ext. 101 or by email at donenber@biosantepharma.com.

CAUTIONARY STATEMENT CONCERNING

FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. All statements other than statements of historical facts included in or incorporated by reference into this prospectus that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like “believe,” “may,” “could,” “might,” “possible,” “potential,” “project,” “will,” “should,” “expect,” “ “predict,” “anticipate,” “estimate,” “approximate,” “contemplate” or “continue” and other words and terms of similar meaning. forward-looking statements generally relate to:

- the timing of the commencement and completion of our clinical trials and other regulatory status of our proposed products;

- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of marketing capabilities and licensure or acquisition of new products;

- whether and how long our existing cash will be sufficient to fund our operations;

- our need and ability to raise additional capital through future equity and other financings; and

- our substantial and continuing losses.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the heading “Risk Factors” included elsewhere in this prospectus.

We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described under the heading “Risk Factors” included elsewhere in this prospectus, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including those described below under the heading “Risk Factors” included elsewhere in this prospectus. The risks and uncertainties described under the heading “Risk Factors” included elsewhere in this prospectus are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

SUMMARY

Our Company

We are a development stage biopharmaceutical company that is developing a pipeline of hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for vaccine adjuvants or immune system boosters and drug delivery systems.

Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone therapies for symptoms that affect both men and women. Symptoms addressed by these hormone therapies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis. The products are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and progestogen.

The gels are designed to be quickly absorbed through the skin after application on the arms, shoulders, abdomen or thighs, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

The following is a list of our hormone therapy gel products:

- Bio-E-Gel - once daily transdermal bioidentical estrogen gel in development for treatment of menopausal symptoms in women.

- LibiGel - once daily transdermal bioidentical testosterone gel in development for treatment of female sexual dysfunction (FSD).

- Bio-E/P-Gel - once daily transdermal combination gel of bioidentical estrogen and a progestogen for treatment of menopausal symptoms in women.

- LibiGel-E/T - once daily transdermal combination gel of bioidentical estrogen and bioidentical testosterone for treatment of FSD in menopausal women.

- Bio-T-Gel - once daily transdermal bioidentical testosterone gel for treatment of hypogonadism, or testosterone deficiency, in men.

We have conducted human clinical trials on several of our hormone therapy products, which are required to obtain U.S. Food and Drug Administration, or FDA, approval to market the products. We completed our pivotal Phase III clinical trial of Bio-E-Gel in March 2005 and submitted our New Drug Application, or NDA, to the FDA in February 2006. We hope to commercially launch our Bio-E-Gel product upon obtaining FDA approval, which we hope to receive in late 2006 or early 2007. Our proposed LibiGel product successfully completed a Phase II clinical trial, and we are currently in the planning stage for our Phase III clinical trials which we hope to begin by year-end 2006. We have not received FDA or any other government approval for any of our products and thus have not commercialized any of them in the United States or elsewhere.

We also are developing our CaP technology, several of whose issued patents we license on an exclusive basis from the University of California, for novel vaccines, including avian flu and biodefense vaccines for toxins such as anthrax and ricin, and drug delivery systems. Our CaP technology is based on the use of extremely small, uniform particles, which we call "nanoparticles." We are pursuing the development of the following potential initial applications for our CaP technology:

- the creation of improved versions of current vaccines and of new vaccines by the "adjuvant" activity of our proprietary nanoparticles that enhance the ability of a vaccine to stimulate an immune response. The same nanoparticles allow for delivery of the vaccine via alternative routes of administration including non-injectable routes of administration; and

- the creation of oral, buccal, intranasal and inhaled delivery of drugs that currently must be given by injection (*e.g.*, insulin).

The following is a list of our CaP products in development:

- BioVant -- proprietary CaP adjuvant and delivery technology in development for improved versions of current vaccines and new vaccines against avian flu and biodefense vaccines such as anthrax and ricin.

- CAP-Oral -- a delivery system using CaP technology for oral/buccal/intranasal administration of proteins and other therapies that currently must be injected.

- BioAir -- a delivery system using CaP technology for inhalable versions of proteins and other therapies that currently must be injected.

Our strategy with respect to CaP is to continue development of our CaP technology and actively seek collaborators and licensees to fund and accelerate the development and commercialization of products incorporating the technology. We have entered into an agreement with the U.S. Army's Medical Research Institute of Infectious Disease for the development of non-injected biodefense vaccines, including anthrax, staph and ricin, and an agreement with DynPort Vaccine Company LLC for the development of anthrax vaccines for delivery via alternative routes of administration, including nasal, oral and needle-free transcutaneous routes. We also have entered into a Material Transfer and Option Agreement for an option to obtain an exclusive, worldwide license to use our CaP in the development of a series of allergy products, a subcontract with the University of Nebraska-Lincoln for the development of recombinant Factor IX formulations for delivery via alternative routes of administration, and an exclusive option and license agreement with Medical Aesthetics Technology Corporation, or MATC, for the use of our CaP technology in the field of aesthetic medicine.

Business Strategy

To enhance the value of our company, we are pursuing the following corporate growth strategies:

- pursuing the development of our hormone therapy products;

- continuing to develop our nanoparticle-based CaP platform technology and seeking assistance in such development through government agencies and corporate partner sublicenses;

- implementing business collaborations or joint ventures with other pharmaceutical and biotechnology companies; and

- licensing or otherwise acquiring other drugs that will add value to our current product portfolio.

Other Information About Our Company

Our company, which was initially formed as a corporation organized under the laws of the Province of Ontario on August 29, 1996, was continued as a corporation under the laws of the State of Wyoming on December 19, 1996 and was reincorporated under the laws of the State of Delaware on June 26, 2001.

Our principal executive offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069. Our telephone number is (847) 478-0500 and our Internet web site address is *www.biosantepharma.com*. The information contained on our web site or connection to our web site is not incorporated by reference into and should not be considered part of this prospectus.

The Offering

Common stock offered by selling stockholders	5,147,520 shares
Use of proceeds	BioSante will not receive any of the proceeds from the sale of the shares offered hereby. See “Use of Proceeds.”
American Stock Exchange Symbol	BPA

RISK FACTORS

This offering involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information contained in this prospectus, or incorporated into this prospectus by reference, including the section entitled "Cautionary Statement Concerning Forward-Looking Statements," before deciding whether to invest in shares of our common stock. If any of the following risks actually occur, our business, financial condition or operating results could be harmed. In that case, the trading price of our common stock could decline, and you may lose part or all of your investment. The risks and uncertainties described below are not the only ones facing BioSante. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations and adversely affect the market price of our common stock.

We have a history of operating losses, expect continuing losses and may never achieve profitability.

We have incurred losses in each year since our amalgamation in 1996 and expect to incur substantial and continuing losses for the foreseeable future. We incurred a net loss of $9,651,036 for the year ended December 31, 2005, and as of December 31, 2005, our accumulated deficit was $49,688,320. We incurred a net loss of $5,453,395 for the six month period ended June 30, 2006, and as of June 30, 2006, our accumulated deficit was $55,141,715.

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and revenue earned from subcontracts. We have not commercially introduced any products. We expect to incur substantial and continuing losses for the foreseeable future as our own product development programs expand and various preclinical and clinical trials commence. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the costs of licensure or acquisition of new products;
- the timing and cost of obtaining necessary regulatory approvals;
- the timing and cost of obtaining third party reimbursement; and
- the timing and cost of sales and marketing activities for future products.

In order to generate new and significant revenues, we must successfully develop and commercialize our own proposed products or enter into collaborative agreements with others who can successfully develop and commercialize them. Even if our proposed products and the products we may license or otherwise acquire are commercially introduced, they may never achieve market acceptance and we may never generate significant revenues or achieve profitability.

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Our cash, cash equivalents and short-term investments as of June 30, 2006 were $4,505,231. On July 21, 2006, we completed a private placement of 3,812,978 shares of our common stock and warrants to purchase 1,334,542 shares of our common stock at a purchase price of $2.00 per share. The private placement resulted in net proceeds of approximately $7.2 million, after deduction of transaction expenses. We believe our cash will be sufficient to fund our operations through at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong. As a result, we will need to raise substantial additional capital to fund our operations sometime in the future.

Our future capital requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of our clinical trials;
- patient recruitment and enrollment in our current and future clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our proposed products;
- our general and administrative expenses;
- if we receive FDA approval of any of our proposed products and choose to commercialize them ourselves, the amount of resources we devote to sales and marketing capabilities;
- the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

Financing may not be available when needed or will be on terms acceptable to us. Insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products, delay the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business.

We are a development stage company, making it difficult for you to evaluate our business and your investment.

We are in the development stage and our operations and the development of our proposed products are subject to all of the risks inherent in the establishment of a new business enterprise, including:

- the absence of an operating history;
- the lack of commercialized products;
- insufficient capital;
- expected substantial and continual losses for the foreseeable future;
- limited experience in dealing with regulatory issues;

· limited marketing and manufacturing experience;

· an expected reliance on third parties for the development and commercialization of some of our proposed products;

· a competitive environment characterized by numerous, well-established and well-capitalized competitors;

· uncertain market acceptance of our proposed products; and

· reliance on key personnel.

Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our company.

Most of our proposed products are in the development stages and will likely not be commercially introduced for one or more years, if at all.

Most of our proposed products are in the development stages and will require further development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. We have not commercially introduced any products and do not expect to do so until early 2007 at the earliest depending upon the timing of the FDA's decision on and approval of our New Drug Application for our Bio-E-Gel product which was submitted in February 2006. We cannot assure you that any of our proposed products will:

· be successfully developed;

· prove to be safe and efficacious in clinical trials;

· meet applicable regulatory standards or obtain required regulatory approvals;

· demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;

· be capable of being produced in commercial quantities at reasonable costs;

· obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or

· be successfully marketed or achieve market acceptance by physicians and patients.

If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed or withdrawn, we will be unable to generate revenue from the sale of our products.

We must obtain regulatory approval to sell any of our products in the United States and abroad. In the United States, we must obtain the approval of the FDA for each product or drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development are approved for sale. Because of the risks and uncertainties in pharmaceutical development, our proposed products could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our management's credibility, the value of our company and our operating results and liquidity would be adversely affected.

Furthermore, even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review. Even after obtaining regulatory approval, we may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or its manufacture are subsequently discovered. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results and financial condition.

To obtain regulatory approval to market our products, costly and lengthy pre-clinical studies and human clinical trials are required, and the results of the studies and trials are highly uncertain.

As part of the FDA approval process, we must conduct, at our own expense or the expense of current or potential licensees, clinical trials on humans on each of our proposed products. Pre-clinical studies on animals must be conducted on some of our proposed products. We expect the number of pre-clinical studies and human clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. We may need to perform multiple pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

After we have conducted pre-clinical studies in animals, we must demonstrate that our products are safe and effective for use on the target human patients in order to receive regulatory approval for commercial sale. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. We face the risk that the results of our clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results would prevent us from filing for regulatory approval of our products. Additional factors that can cause delay or termination of our human clinical trials include:

- slow patient enrollment;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- longer treatment time required to demonstrate efficacy or safety;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the product being tested.

Delays in our clinical trials could allow our competitors additional time to develop or market competing products and thus can be extremely costly in terms of lost sales opportunities and increased clinical trial costs.

A request by an FDA advisory committee for additional safety data which may require Procter & Gamble to conduct additional studies to learn more about the long-term safety of testosterone treatment in women for FSD prior to granting approval of Procter & Gamble's Intrinsa testosterone patch could increase the time, cost and expense of obtaining regulatory approval for our LibiGel product, which might cause us to abandon the product depending on the extent of the additional time and cost to develop LibiGel.

In December 2004, the FDA's Reproductive Health Drugs Advisory Committee panel voted unanimously against recommendation for approval of Procter & Gamble's Intrinsa testosterone patch for hypoactive sexual desire disorder. The panel's main concern was the desire to have long-term safety data particularly as it pertains to potential increased risk of cardiovascular disease and breast cancer in women treated chronically with testosterone in combination with estrogen. Currently, the FDA has not explicitly publicly stated nor set any type of public policy or guidance document as to what size or duration of a safety trial would be required for approval. This FDA action with respect to Intrinsa or testosterone products in general may affect the regulatory pathway for our LibiGel product, as well as other similarly competitive products to treat HSDD with testosterone therapy. The FDA's final decision could increase the time, cost and expense of obtaining regulatory approval for our LibiGel product, which might cause us to delay or abandon further development of the product depending on the extent of the additional time and cost to develop LibiGel.

Several pharmaceutical products have been found to have potentially life threatening side effects and have been subsequently removed from the market. These drugs had been previously approved for sale by the FDA. The withdrawals of approved drugs from the market create an increased risk for the pharmaceutical industry in general in that certain proposed products may not receive the required regulatory approval on a timely basis or ever. The withdrawal of Vioxx by Merck & Co., Inc. has increased safety concerns of various groups including physicians, patients, members of U.S. Congress and the FDA. Although marketed product withdrawals have occurred over time, these withdrawals have resulted and may continue to result in a more cautious approach by the FDA in terms of requirements for approval of new products before approval to market is granted. These recent withdrawals could also result in additional requirements for safety monitoring called pharmacovigilence after approval to market is granted. This collective concern could result in longer, more expensive clinical trials before approval and costly post-marketing surveillance programs and at the same time could affect physicians' desire to prescribe new medication before they are on the market for a long period of time, all of which would adversely affect our business, operating results and financial condition.

Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the market for hormone therapy products and the trading price of our common stock.

The market for hormone therapy products has been negatively affected by the Women's Health Initiative study and other studies that have found that the overall health risks from the use of certain hormone therapy products exceed the benefits from the use of those products among healthy postmenopausal women. In July 2002, the National Institutes of Health (NIH) released data from its Women's Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced.

The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom was also halted. Our proposed hormone therapy products differ from the products used in the Women's Health Initiative study and the primary products observed in the National Cancer Institute and United Kingdom studies. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment. Researchers continue to analyze data from both arms of the WHI study and other studies. Recent reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. There currently are no studies published comparing the safety of our proposed hormone therapy products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms have declined as a result of these published studies. The release of any follow-up or other studies that show adverse affects from hormone therapy, including in particular, hormone therapies similar to our proposed products, would also adversely affect our business.

Because our industry is very competitive and many of our competitors have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us, we may not succeed in developing our proposed products and bringing them to market.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us. Academic institutions, hospitals, governmental agencies and other public and private research organizations are also conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. We cannot assure you that our competitors (some of whom are our development partners) will not succeed in developing similar technologies and products more rapidly than we do, commercially introducing such technologies and products to the marketplace prior than us, or that these competing technologies and products will not be more effective or successful than any of those that we currently are developing or will develop.

We license the technology underlying most of our proposed hormone therapy products and a portion of our CaP technology from third parties and may lose the rights to license them, which could have a material adverse effect on our business, financial position and operating results and could cause the market value of our common stock to decline.

We license most of the technology underlying our proposed hormone therapy products from Antares Pharma, Inc. and a portion of our CaP technology from the University of California. We may lose our right to license these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California's license agreement within 60 days after written notice from the University of California, the other party to these agreements may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees owing at the time of termination. Our failure to retain the right to license the technology underlying our proposed hormone therapy products or CaP technology could harm our business and future operating results.

For example, if we were to enter into an outlicense agreement with a third party under which we agree to outlicense our hormone therapy technology or CaP technology for a license fee, the termination of the main license agreement with Antares Pharma, Inc. or the University of California could either, depending upon the terms of the outlicense agreement, cause us to breach our obligations under the outlicense agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the outlicense fees.

We have licensed two of our proposed hormone therapy products to third parties and any breach by these parties of their obligations under these sublicense agreements or a termination of these sublicense agreements by these parties could adversely affect the development and marketing of our licensed products. In addition, these third parties also may compete with us with respect to some of our proposed products.

We have licensed two of our proposed hormone therapy product to third parties, Solvay Pharmaceuticals, B.V. and Teva Pharmaceuticals USA, Inc., which have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products. In addition, we may in the future enter into additional similar license agreements. Our partnered products that we have licensed to others are thus subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of products, but also depend on the respective licensees for timely development, obtaining required regulatory approvals, commercialization and otherwise continued commitment to the products. Our current and future licensees may have different and, sometimes, competing priorities. Teva USA has discontinued development of Bio-T-Gel and indicated to us a desire to formally terminate this agreement. Accordingly, we are in the process of exploring various alternatives with respect to our Bio-T-Gel product, including licensing the product to another third party or continuing the development of the product ourselves. We cannot assure you that Solvay or any future third party to whom we may license our proposed products will remain focused on the development and commercialization of our partnered products or will not otherwise breach the terms of our agreements with them, especially since these third parties may also compete with us with respect to some of our proposed products. Any breach by Solvay or any other third party of their obligations under these agreements or a termination of these agreements by these parties could adversely affect development of the products in these agreements if we are unable to sublicense the proposed products to another party on substantially the same or better terms or continue the development and future commercialization of the proposed products ourselves.

We do not have any facilities appropriate for clinical testing, we lack significant manufacturing experience and we have very limited sales and marketing personnel. We are currently dependent upon our licensees or others for several of these functions and may remain dependent upon others for these functions.

We do not have a manufacturing facility that can be used for production of our products. In addition, at this time, we have very limited sales and marketing personnel. We are currently dependent upon our licensees or others for several of these functions. In the course of our development program, we may be required to enter into additional arrangements with other companies, universities or clinical investigators for our animal testing, human clinical testing, manufacturing and sales and marketing activities. Alternatively, we may decide to add additional personnel and perform some of these functions ourselves, such as sales and marketing activities. If our licensees or other third parties in which we have entered into agreements breach their obligations under our agreements to perform these functions or if we are otherwise unable to retain third parties for these purposes on acceptable terms or perform such functions successfully ourselves, we may be unable to successfully develop, manufacture and market our proposed products.

In addition, any failures by our licensees or other third parties to adequately perform their responsibilities may delay the submission of our proposed products for regulatory approval, impair our ability to deliver our products on a timely basis or otherwise impair our competitive position. Our dependence on our licensees and other third parties for the development, manufacture, sale and marketing of our products also may adversely affect our profit margins.

Even if our proposed products receive FDA approval, they may not achieve expected levels of market acceptance, which could have a material adverse effect on our business, financial position and operating results and could cause the market value of our common stock to decline.

Even if we are able to obtain required regulatory approvals for our proposed products, the success of those products is dependent upon market acceptance by physicians and patients. Levels of market acceptance for our new products could be impacted by several factors, including:

- the availability of alternative products from competitors;
- the price of our products relative to that of our competitors;
- the timing of our market entry; and
- the ability to market our products effectively.

Some of these factors are not within our control. Our proposed products may not achieve expected levels of market acceptance. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future result, in the discontinuance of product marketing. These situations, should they occur, could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

Because the pharmaceutical industry is heavily regulated, we face significant costs and uncertainties associated with our efforts to comply with applicable regulations. Should we fail to comply we could experience material adverse effects on our business, financial position and results of operations, and the market value of our common stock could decline.

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For example, we must comply with FDA requirements with respect to the development of our proposed products and our clinical trials, and if any of our proposed products are approved, the manufacture, labeling, sale, distribution, marketing, advertising and promotion of our products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

If we are unable to protect our proprietary technology, we may not be able to compete as effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, upon our ability to obtain, enjoy and enforce protection for any products we develop or acquire under United States and foreign patent laws and other intellectual

property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties.

Where appropriate, we seek patent protection for certain aspects of our technology. However, our owned and licensed patents and patent applications may not ensure the protection of our intellectual property for a number of other reasons:

- We do not know whether our licensor's patent applications will result in issued patents.

- Competitors may interfere with our patents and patent process in a variety of ways. Competitors may claim that they invented the claimed invention before us or may claim that we are infringing on their patents and therefore we cannot use our technology as claimed under our patent. Competitors may also have our patents reexamined by showing the patent examiner that the invention was not original or novel or was obvious.

- We are in the development stage and are in the process of developing proposed products. Even if we receive a patent, it may not provide much practical protection. If we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent. Even if the development of our proposed products is successful and approval for sale is obtained, there can be no assurance that applicable patent coverage, if any, will not have expired or will not expire shortly after this approval. Any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our proposed product.

- Enforcing patents is expensive and may require significant time by our management. In litigation, a competitor could claim that our issued patents are not valid for a number of reasons. If the court agrees, we would lose protection on products covered by those patents.

- We also may support and collaborate in research conducted by government organizations or universities. We cannot guarantee that we will be able to acquire any exclusive rights to technology or products derived from these collaborations. If we do not obtain required licenses or rights, we could encounter delays in product development while we attempt to design around other patents or we may be prohibited from developing, manufacturing or selling products requiring these licenses. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

It also is unclear whether efforts to secure our trade secrets will provide useful protection. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors resulting in a loss of protection. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

Claims by others that our products infringe their patents or other intellectual property rights could adversely affect our financial condition.

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States and also are maintained in secrecy outside the United States until the application is published. Accordingly, we can conduct only limited searches to determine whether our technology infringes the patents or patent applications of others. Any claims of patent infringement asserted by third parties would be time-consuming and could likely:

· result in costly litigation;

· divert the time and attention of our technical personnel and management;

· cause product development delays;

· require us to develop non-infringing technology; or

· require us to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results.

We have very limited staffing and will continue to be dependent upon key employees.

Our success is dependent upon the efforts of a small management team and staff. We have employment arrangements in place with all of our executive officers, but none of our executive officers is legally bound to remain employed for any specific term. Although we have key man life insurance on our President and Chief Executive Officer, Stephen M. Simes, we do not have key man life insurance policies covering any of our other executive officers or employees. If key individuals leave BioSante, we could be adversely affected if suitable replacement personnel are not quickly recruited. There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the development and growth of our business. Our future success depends upon our ability to continue to attract and retain qualified personnel.

The price and trading volume of our common stock has been, and may continue to be, volatile.

Historically, the market price and trading volume of our common stock has fluctuated over a wide range. During the past 12 months, our common stock traded in a range from a low of $1.75 to a high of $4.80, and our daily trading volume ranged from 4,500 shares to 1,001,300 shares. It is likely that the price and trading volume of our common stock will continue to fluctuate in the future. The securities of small capitalization, biopharmaceutical companies, including our company, from time to time experience significant price and volume fluctuations, often unrelated to the operating performance of these companies. In particular, the market price and trading volume of our common stock may fluctuate significantly due to a variety of factors, including:

· governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products or our competitors' products;

· the results of our clinical trials or those of our competitors;

· announcements of technological innovations or new products by us or our competitors;

· announcements by licensors or licensees of our technology;

- public concern as to the safety or efficacy of or market acceptance of products developed by us or our competitors;

- developments or disputes concerning patents or other proprietary rights;

- our ability to obtain needed financing;

- period-to-period fluctuations in our financial results, including our cash, cash equivalents and short-term investment balance, operating expenses, cash burn rate or revenues;

- loss of key management;

- common stock sales in the public market by one or more of our larger stockholders, officers or directors;

- other potentially negative financial announcements, including delisting of our common stock from the American Stock Exchange, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC; and

- economic conditions in the United States and abroad.

In addition, the occurrence of any of the risks described above or elsewhere in this prospectus or otherwise in reports we file with or submit to the SEC from time to time could have a material and adverse impact on the market price of our common stock. For example, in December 2004, primarily as a result of the unanimous vote by the FDA's Reproductive Health Drugs Advisory Committee panel against recommendation for approval of Procter & Gamble's Intrinsa testosterone patch for hypoactive sexual desire disorder, the price of our common stock decreased over 35% in one trading day and over 50% over the course of three trading days. In addition, on the day of and first two trading days after the public announcement of FDA advisory panel's recommendation, the daily trading volume of our common stock went from an average of approximately 166,000 shares per day to an average of over approximately 3 million shares per day for those same three days and then back down to an average of approximately 140,000 shares per day.

Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. We may become the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our stock price.

We are in the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which will become applicable to BioSante beginning with our fiscal year ended December 31, 2007 or one year later if currently proposed SEC rules are adopted. Section 404 of the Sarbanes-Oxley Act requires annual management assessment of the effectiveness of our internal controls over financial reporting (ICFR) a report by our registered independent public accounting firm addressing management's assessment and independent audit of ICFR. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. While we feel that our key controls are currently effective, we have not yet completed a formal assessment of our ICFR.

We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effects on our operations, although we expect such activities will require management time and resources. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission or the American Stock Exchange. Any such action could adversely affect our financial results, financial position and the market price of our common stock. In addition, if one or more material weaknesses is identified in ICFR, we will be unable to assert that our ICFR is effective. If we are unable to assert that our ICFR is effective (or if our auditors are unable to attest that management's report is fairly stated, they are unable to express an opinion on our management's evaluation or on the effectiveness of the internal controls or they issue an adverse opinion on ICFR), we could lose investor confidence in the accuracy and completeness of our financial reports, which in turn could have an adverse effect on our stock price. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective ICFR in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective ICFR could have an adverse effect on our common stock price.

Sales of a substantial number of shares of our common stock in the public market, including the shares offered under this prospectus and under other registration statements, could lower our stock price and impair our ability to raise funds in new stock offerings.

Future sales of a substantial number of shares of our common stock in the public market, including the shares offered under this prospectus, other registration statements and shares available for resale under Rule 144(k) under the Securities Act, or the perception that such sales could occur, could adversely affect the prevailing market price of our common stock and could make it more difficult for us to raise additional capital through the sale of equity securities.

We may incur significant costs from class action litigation due to our expected stock volatility.

In the past, following periods of large price declines in the public market price of a company's stock, holders of that stock occasionally have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring this type of lawsuit against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit also could divert the time and attention of our management, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Provisions in our charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions include:

· authorizing the issuance of "blank check" preferred that could be issued by our Board of Directors to increase the number of outstanding shares and thwart a takeover attempt;

- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and

- advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

Our directors and executive officers own a sufficient number of shares of our capital stock to control our company, which could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Our directors and executive officers own or control approximately 17.0% of our outstanding voting power. Accordingly, these stockholders, individually and as a group, may be able to influence the outcome of stockholder votes, involving votes concerning the election of directors, the adoption or amendment of provisions in our certificate of incorporation and bylaws and the approval of certain mergers or other similar transactions, such as a sale of substantially all of our assets. Such control by existing stockholders could have the effect of delaying, deferring or preventing a change in control of our company.

Exercise of outstanding options and warrants will dilute stockholders and could decrease the market price of our common stock.

As of August 17, 2006, we had issued and outstanding 22,973,672 shares of common stock, 391,286 shares of our class C stock and outstanding options and warrants to purchase 3,624,689 additional shares of common stock. The existence of the outstanding options and warrants may adversely affect the market price of our common stock and the terms under which we could obtain additional equity capital.

We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on your investment in our common stock must come from increases in the fair market value and trading price of our common stock.

We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on your investment in our common stock must come from increases in the fair market value and trading price of our common stock.

We likely will issue additional equity securities which will dilute your share ownership.

We likely will issue additional equity securities to raise capital and through the exercise of options and warrants that are outstanding or may be outstanding. These additional issuances will dilute your share ownership.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares offered under this prospectus by the selling stockholders. This offering is intended to satisfy our obligations to register, under the Securities Act of 1933, the resale of the shares of our common stock, including shares of our common stock that will be issued to the selling stockholders upon the exercise of warrants held by them that we issued to the selling stockholders in a private placement.

SELLING STOCKHOLDERS

All of the selling stockholders named below acquired or have the right to acquire upon the exercise of warrants the shares of our common stock being offered under this prospectus directly from us in a private placement completed in July 2006. The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of July 25, 2006 as provided by the selling stockholders. In accordance with the rules of the SEC, beneficial ownership includes the shares issuable pursuant to warrants that are exercisable within 60 days of July 25, 2006. Shares issuable pursuant to warrants are considered outstanding for computing the percentage of the person holding the warrants but are not considered outstanding for computing the percentage of any other person. The warrants issued in July 2006 become exercisable on January 22, 2007 and are subject to a conversion cap which precludes the holder thereof from exercising such warrants to the extent that such owner would beneficially own in excess of 4.99% or 9.99% of BioSante's common stock. These warrants are included in shares beneficially owned prior to the offering.

The percentage of beneficial ownership for the following table is based on 22,973,672 shares of common stock outstanding as of July 25, 2006. To our knowledge, except as indicated in the footnotes to this table, each person named in the table has sole voting and investment power with respect to all shares of common stock shown in the table to be beneficially owned by such person.

Except as set forth below, none of the selling stockholders has had any position, office or other material relationship with us within the past three years. The table assumes that the selling stockholders will sell all of the shares offered by them in this offering. However, we are unable to determine the exact number of shares that will actually be sold or when or if these sales will occur. We will not receive any of the proceeds from the sale of the shares offered under this prospectus.

	Shares Beneficially Owned Prior to the Offering				Shares Beneficially Owned After Completion of the Offering	
Selling Stockholder	Shares Subject to Warrants	Total Shares Beneficially Owned	Percentage	Number of Shares Being Offered	Number	Percentage
Bristol Investment Fund, Ltd. (1)	52,500	202,500	*	202,500	0	--
Clarion Capital Corporation (2)	43,750	168,750	*	168,750	0	--
Crescent International Ltd. (3)	52,500	202,500	*	202,500	0	--
Crestview Capital Master, LLC (4)	175,000	675,000	2.9%	675,000	0	
Diamond Opportunity Fund, LLC (5)	43,750	168,750	*	168,750	0	--
Hermann S. Graf zu Muenster	12,750	162,335	*	33,750	128,585	*
Hunt BioVentures, L.P. (6)	87,500	337,500	1.5%	337,500	0	--
Iroquois Master Fund Ltd. (7)	43,750	168,750	*	168,750	0	--
James S. Levy Trust dtd. 2/1/99 (8)	8,750	33,750	*	33,750	0	--
Joseph S. Levy	4,375	16,875	*	16,875	0	--
Mallette Capital Master Fund Ltd. (9)	48,706	553,524	2.4%	187,866	365,658	1.6%
Mallette Capital Biotech Fund LP (9)	21,294	241,876	1.1%	82,134	159,742	*
Roscoe F. Nicholson II Profit Sharing (10)	20,925	246,734	1.1%	16,875 (11)	196,109	*
Nite Capital L.P. (12)	65,792	253,770	1.1%	253,770	0	--
Panacea Fund, LLC (13)	97,750	342,750	1.5%	87,750	255,000	1.1%
Perceptive Life Sciences Master Fund, Ltd. (14)	272,500	772,500	3.3%	675,000	97,500	*
Quogue Capital LLC (15)	98,750	348,750	1.5%	337,500	11,250	*
RAQ, LLC (16)	35,000	135,000	*	135,000	0	--
SF Capital Partners Ltd. (17)	175,000	675,000	2.9%	675,000	0	--
Sheffield Partners, L.P. (18)	11,013	150,866	*	42,478	108,388	*
Sheffield Institutional Partners, L.P. (18)	17,078	233,812	1.0%	65,873	167,939	*
Sheffield International Partners, Ltd. (18)	15,659	214,443	*	60,399	154,044	*
Valesco Healthcare Master Fund, L.P. (19)	52,500	202,500	*	202,500	0	--
	82,250	966,950	4.2%	317,250	649,700	2.8%

WHI Growth Fund Q.P.,
L.P. (20)

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* Less than one percent (1%)

(1) Bristol Capital Advisors, LLC is the investment advisor to Bristol Investment Fund, Ltd. Paul Kessler is the manager of Bristol Capital Advisors, LLC and as such has voting and investment control over the securities held by Bristol Investment Fund, Ltd. Mr. Kessler disclaims beneficial ownership of these securities.

(2) Morton A. Cohen is Chairman of Clarion Capital Corporation, and as such has authority to vote and dispose of securities held by Clarion Capital Corporation.

(3) Cantara (Switzerland) SA is the investment advisor to Crescent International Ltd. Maxi Brezzi and Bachir Taleb-Ibrahimi are managers of Cantara (Switzerland) SA, and as such have authority to vote and dispose of the securities held by Crescent International Ltd. Messrs. Brezzi and Taleb-Ibrahimi disclaim beneficial ownership of such securities.

(4) Crestview Capital Partners, LLC is the sole manager for Crestview Capital Master, LLC. The power to vote or dispose of the shares beneficially owned by Crestview Capital Master, LLC is shared by Stewart Flink, Robert Hoyt and Daniel Warsh, each of whom disclaim beneficial ownership of the shares beneficially owned by Crestview Capital Master, LLC. Stewart Flink, a manager of Crestview Capital Partners, LLC, is the controlling shareholder of Dillon Capital Inc., a registered broker-dealer. Crestview Capital Master, LLC has represented to us that it purchased the shares being offered under this prospectus in the ordinary course of business, and at the time of purchase, had no agreements or understandings to distribute the shares.

(5) David Hokin, Rob Rubin and Richard Marks, in their respective capacity as manager and managing Directors of Diamond Opportunity Fund, LLC, have shared voting and investment control over the shares held by Diamond Opportunity Fund, LLC. Messrs. Hokin, Rubin and Marks disclaim beneficial ownership of such securities.

(6) Christopher W. Kleinert has sole investment and voting power over the shares of BioSante common stock held by Hunt BioVentures, L.P.

(7) Joshua Silverman has voting and investment control over the shares held by Iroquois Master Fund Ltd. Mr. Silverman disclaims beneficial ownership of such securities.

(8) James S. Levy as trustee of the James S. Levy Trust dtd. 2/1/99 has voting and investment power over the securities beneficially owned by the James S. Levy Trust dtd. 2/1/99. James S. Levy is a registered broker-dealer and has represented to us that the James S. Levy Trust dtd. 2/1/99 has purchased the shares being offered under this prospectus in the ordinary course of business, and at the time of purchase, had no agreements or understandings to distribute the shares.

(9) Mallette Capital Management, Inc. is the investment advisor of Mallette Capital Master Fund Ltd. and Mallette Capital Biotech Fund L.P. and consequently has voting control and investment discretion over securities owned by Mallette Capital Master Fund Ltd. and Mallette Biotech Fund L.P. Quinterol Mallette, M.D. is the President of Mallette Capital Management, Inc. As a result, Mallette Capital Management, Inc. and Dr. Mallette may be considered the beneficial owner of any shares deemed to be beneficially owned by Mallette Capital Master Fund Ltd. and Mallette Biotech Fund L.P.

(10) Mr. Nicholson’s beneficial ownership includes: (1) 7,175 shares of common stock issuable upon exercise of warrants, (2) 16,532 shares of common stock and 1,000 shares of common stock issuable upon exercise of a warrant held by Mr. Nicholson’s spouse, (3) 13,642 shares of common stock held by Mr. Nicholson’s children, of which Mr. Nicholson shares voting and dispositive power and (4) 149,585 shares of common stock and 12,750 shares of common stock issuable upon exercise of warrants held by Hermann S. Graf zu Muenster, of which Mr. Nicholson serves as an advisor and shares dispositive power over these shares.

(11) Does not include shares being offered by Hermann S. Graf zu Muenster.

(12) Nite Capital, LLC, is the general partner of Nite Capital, L.P. Keith A. Goodman is the manager of Nite Capital, LLC, and as such has authority to vote and dispose of the securities held by Nite Capital, L.P. Mr. Goodman disclaims beneficial ownership of such securities.

(13) Michael S. Resnick, executive vice president of William Harris Investors Inc., the manager of the selling stockholder, and Charles Polsky, a fund manager of the selling stockholder, share voting and investment control with respect to the shares offered by the selling stockholder.

(14) Perceptive Advisors, LLC, is the investment manager of Perceptive Life Science Master Fund, Ltd. and consequently has voting control and investment discretion over securities owned by Perceptive Life Science Master Fund, Ltd. Joseph Edelman is the managing member of Perceptive Advisors, LLC. As a result, Mr. Edelman may be considered the beneficial owner of any shares deemed to be beneficially owned by Perceptive Life Science Master Fund, Ltd. Perceptive Life Science Master Fund, Ltd. was a 10% or more stockholder of BioSante within the last three years.

(15) Wayne Rothbaum, a principal of Quogue Capital LLC, has voting and investment power over the securities beneficially owned by Quogue Capital LLC.

(16) Lindsay A. Rosenwald, M.D., is the managing and sole member of RAQ, LLC, and as such has authority to vote and dispose of the securities held by RAQ, LLC. Dr. Rosenwald is the sole shareholder and chairman of Paramount BioCapital, Inc., a registered broker-dealer and Paramount BioCapital Asset Management, Inc., an investment advisor. RAQ, LLC has indicated to us that it purchased the shares being offered under this prospectus in the ordinary course of business and, at the time of purchase, had no agreements or understandings to distribute the shares.

(17) Michael A. Roth and Brian J. Stark have voting and investment control over the securities held by SF Capital Partners Ltd., but disclaim beneficial ownership of such securities. SF Capital Partners Ltd. is an affiliate of Reliant Trading and Shepherd Trading Limited, each of which is a registered broker-dealer. SF Capital Partners Ltd. has represented to us to us that it purchased the shares being offered under this prospectus in the ordinary course of business and, at the time of purchase, did not have any plans or proposals, directly or with another person, to distribute the shares.

(18) Brian J. Feltzin and Craig C. Albert are the members of Sheffield Asset Management, L.L.C., the general partner of Sheffield Partners, L.P. and Sheffield Institutional Partners, L.P. and the investment advisor to Sheffield International Partners, Ltd., and consequently have voting control and investment discretion over securities owned by Sheffield Partners, L.P., Sheffield Institutional Partners, L.P. and Sheffield International Partners, Ltd. As a result, Brian J. Feltzin and Craig C. Albert may be considered the beneficial owners of any shares deemed to be beneficially owned by Sheffield Partners, L.P., Sheffield Institutional Partners, L.P. and Sheffield International Partners, Ltd.

(19) Valesco Healthcare GP, LLC is the general partner to Valesco Healthcare Master Fund, L.P. I. Keith Maher, M.D., is a member and the portfolio manager of Valesco Healthcare GP, LLC, and as such has authority to vote and dispose of the securities held by Valesco Healthcare Master Fund, LP. Lindsay A. Rosenwald, M.D. is the managing member of Valesco Healthcare GP, LLC. Dr. Rosenwald is the sole shareholder and chairman of Paramount BioCapital, Inc., a registered broker-dealer, and Paramount BioCapital Asset Management, Inc., an investment advisor. Dr. Maher is a managing director of Paramount BioCapital Asset Management, Inc. Valesco Healthcare Master Fund, LP has represented to us that it purchased the shares being offered under this prospectus in the ordinary course of business and, at the time of purchase, had no agreements or understandings to distribute the shares.

(20) William Harris Investors, Inc. is the general partner to WHI Growth Fund Q.P., L.P. Michael S. Resnick, executive vice president of William Harris Investors, Inc., has investment and voting power over the shares of BioSante common stock held by WHI Growth Fund Q.P., L.P.

PLAN OF DISTRIBUTION

Each selling stockholder of the common stock and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on the American Stock Exchange or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of the common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

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The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume limitations by reason of Rule 144(k) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for BioSante by Oppenheimer Wolff & Donnelly LLP, Minneapolis, Minnesota.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

BioSante's Certificate of Incorporation limits the liability of its directors to the fullest extent permitted by the Delaware General Corporation Law. Specifically, Article VII of BioSante's Certificate of Incorporation provides that no director of BioSante shall be personally liable to BioSante or its stockholders for monetary damages for any breach of fiduciary duty by such a direc