

BIOSANTE PHARMACEUTICALS INC

Form POS AM

February 06, 2004

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As filed with the Securities and Exchange Commission on February 6, 2004

Registration No. 333-64218

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

POST-EFFECTIVE AMENDMENT NO. 3
ON

FORM S-3
TO
FORM SB-2/A

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

58-2301143
(I.R.S. Employer
Identification Number)

111 Barclay Boulevard
Lincolnshire, Illinois 60069
Telephone No.: (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
Telephone No.: (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:

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:

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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 delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

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.

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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 February 6, 2004

PROSPECTUS

9,542,221 Shares

Common Stock

Selling stockholders of BioSante Pharmaceuticals, Inc. are offering 9,542,221 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 22.

Our common stock is listed on the American Stock Exchange under the symbol **BPA**. On February 5, 2004, the last sale price of our common stock on the American Stock Exchange was \$ _____ per share.

The common stock offered involves a high degree of risk. We refer you to **Risk Factors, beginning on page 8.**

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 _____, 2004

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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-T-Gel , Bio-E-Gel , Bio-E/P-Gel , LibiGel and LibiGel-E/T .

On May 31, 2002, we effected a one-for-ten reverse split of our issued and outstanding shares of common stock and class C stock. All share and per share numbers in this prospectus have been adjusted to reflect the reverse stock split.

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.

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WHERE YOU CAN FIND MORE INFORMATION

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:

Judiciary Plaza
450 Fifth Street, N.W.
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, 450 Fifth Street, N.W., 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.biosantepharm.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.

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.

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 them, 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:

our Annual Report on Form 10-KSB for the year ended December 31, 2002;

our Quarterly Reports on Form 10-QSB for the quarters ended March 31, 2003, June 30, 2003 and September 30, 2003;

our Current Reports on Form 8-K filed on August 6, 2003, September 19, 2003 and September 25, 2003; and

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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 until this distribution is completed.

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

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**CAUTIONARY STATEMENT CONCERNING
FORWARD-LOOKING STATEMENTS**

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements concerning our financial condition, results of operations and business, including, without limitation, statements pertaining to:

our substantial and continuing losses;

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;

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

our raising of additional capital through future equity financings.

Generally, you can identify these statements because they use phrases like anticipates, believes, expects, future, intends, plans, and similar. These statements are only predictions. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy, and actual results may differ materially from those we anticipated due to a number of uncertainties, many of which are unforeseen. You should not place undue reliance on these forward-looking statements, which apply only as of the date such statements are made. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, among others, the risks we face, as described in the section entitled Risk Factors and in documents we incorporate into this prospectus by reference.

We believe it is important to communicate our expectations to our investors. There may be events in the future, however, that we are unable to predict accurately or over which we have no control. The risk factors listed in the section entitled Risk Factors, as well as any cautionary language in this prospectus and in documents we incorporate into this prospectus by reference, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the section entitled Risk Factors and in documents we incorporate into this prospectus by reference could negatively impact our business, operating results, financial condition and stock price.

We are not obligated to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as otherwise required by law. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus and in documents we incorporate into this prospectus by reference and other statements made from time to time from us or our representatives, might not occur. For these statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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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, nanoparticulate-based platform technology, or CAP, for vaccine adjuvants or immune system boosters, drug delivery systems and the purification of the milk of transgenic animals.

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 we in-license from Antares Pharma, Inc. are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), combinations of estradiol and testosterone and estradiol and progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, shoulders, abdomen or thighs, delivering the required 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.

Our Products

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

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

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

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

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

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

Our CAP technology, a portion of which we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call nanoparticles, as adjuvants or immune system boosters, for drug delivery and to purify the milk of transgenic animals. We have identified three 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;

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the creation of oral and inhaled forms of drugs that currently must be given by injection (*e.g.*, insulin); and

the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown.

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

BioVant proprietary CAP adjuvant technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases, among others.

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

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

CAP biotechnology production use of CAP technology in a new patented process for extracting therapeutic proteins from the milk of transgenic animals.

Our Growth 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 platform technology, or CAP, and seeking assistance in such development through corporate partner sub-licenses;

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, Suite 280, Lincolnshire, Illinois 60069, and our telephone number is (847) 478-0500. Our web site is located at 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.

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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.

Risks Relating to Our Company

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 \$3,810,690 for the year ended December 31, 2002, and as of December 31, 2002, our accumulated deficit was 22,061,723. We incurred a net loss of \$4,299,686 for the nine months ended September 30, 2003, and as of September 30, 2003, our accumulated deficit was \$26,361,409.

All of our revenue to date has been derived from interest earned on invested funds and up-front and milestone payments earned on licensing and sub-licensing transactions. 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 and continue. 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; and
- the timing and cost of obtaining third party reimbursement.

In order to generate revenues, we must successfully develop and commercialize our own proposed products or products in the late-stage human clinical development phase or already on the market that we may in-license or otherwise acquire, 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 revenues or achieve profitability.

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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. Therefore, we will need to raise substantial additional capital to fund our operations sometime in the future. We cannot be certain that any financing will be available when needed. If we fail to raise additional financing as we need it, we may have to delay or terminate our product development programs or pass on opportunities to in-license or otherwise acquire new products that we believe may be beneficial to our business.

Our cash on hand as of September 30, 2003 was \$10,396,015. We believe this cash will be sufficient to fund our operations through December 2004. We have based this estimate on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. Any additional equity financings may be dilutive to our existing stockholders and involve the issuance of securities that may have rights, preferences or privileges senior to those possessed by our current stockholders. A debt financing, if available, may involve restrictive covenants on our business which could limit our operational and financial flexibility, and the amount of debt incurred could make us more vulnerable to economic downturns and limit our ability to compete. We cannot be certain that any financing will be available when needed or will be on terms acceptable to us. In addition, insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate 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;
- the lack of manufacturing experience and limited marketing 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; and
- reliance on key personnel.

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

Our proposed products are in the research and development stages and will likely not be commercially introduced for several years, if at all.

Our proposed products are in the research and development stages and will require further research and development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. 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;

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; or

be successfully marketed.

Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the trading price of our shares.

In July 2002, the National Institutes of Health released data from its Women's Health Initiative study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The National Institutes of Health 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. There are, however, no studies comparing the safety of our proposed hormone therapy products against other hormone therapies.

If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed, 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.

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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 biopharmaceutical 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.

To obtain regulatory approval to market our products, costly and lengthy preclinical studies and clinical trials will be required, and the results of the studies and trials are highly uncertain.

As part of the FDA approval process, we must conduct preclinical studies on animals and clinical trials on humans on each of our proposed products. We expect the number of preclinical studies and 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 preclinical studies using various doses and formulations before we can begin clinical trials, which could result in delays in our ability to obtain any regulatory approvals or to market any of our products. Furthermore, even if we obtain favorable results in preclinical studies on animals, the results in humans may be different.

After we have conducted preclinical studies in animals, we must demonstrate that our products are safe and effective for use on human patients in order to receive regulatory approval for commercial sale. The data obtained from preclinical and clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. Adverse or inconclusive clinical results would prevent us from filing for regulatory approval of our products. Additional factors that could cause delay or termination of our clinical trials include:

slow patient enrollment;

longer treatment time required to demonstrate efficacy;

adverse medical events or side effects in treated patients; and

lack of effectiveness of the product being tested.

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.

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

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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 do not have any facilities appropriate for clinical testing, we lack significant manufacturing experience and we have very limited sales and marketing personnel. We may, therefore, be dependent upon others for our clinical testing, manufacturing, sales and marketing.

Our current facilities do not include accommodation for the testing of our proposed products in animals or in humans for the clinical testing required by the FDA. We do not have a manufacturing facility that can be used for full-scale production of our products. In addition, at this time, we have very limited sales and marketing personnel. In the course of our development program, we will therefore be required to enter into arrangements with other companies or universities for our animal testing, human clinical testing, manufacturing, and sales and marketing activities. If we are unable to retain third parties for these purposes on acceptable terms, we may be unable to successfully develop, manufacture and market our proposed products. In addition, any failures by 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 third parties for the development, manufacture, sale and marketing of our products also may adversely affect our profit margins.

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. In February 2000, we filed a patent application relating to our CAP technology. However, our owned and licensed patents and patent applications may not definitively ensure the protection of our intellectual property for a number of other reasons that are beyond our control. For example:

We do not know whether our patent applications will result in actual patents. For example, we may not have developed a method for treating a disease or manufacturing a product before others have developed similar methods.

Competitors may interfere with our 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 contest our patents by showing the patent examiner that the invention was not original or novel or was obvious.

We are in the research and 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.

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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 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 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. 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 until the patents are issued and also are maintained in secrecy for a period of time outside the United States. Accordingly, we can conduct only limited searches to determine whether our technology infringes any patents or patent applications of others. Any claims of patent infringement 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.

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Because we are developing new products, we may fail to gain market acceptance for our products and our business could suffer.

None of the products we propose to develop or are developing have yet been approved for marketing by regulatory authorities in the United States or elsewhere. Even if our proposed products ultimately are approved for sale, there can be no assurance that they will be commercially successful.

Risks Relating to Our Industry

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 are numerous and include pharmaceutical 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 also are 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 will not succeed in developing similar technologies and products more rapidly than we do or that these competing technologies and products will not be more effective than any of those that we currently are developing or will develop.

We are dependent upon key personnel, many of whom would be difficult to replace.

Our success will be largely dependent upon the efforts of Stephen M. Simes, our Vice Chairman, President and Chief Executive Officer, and other key employees. Our future success also will depend in large part upon our ability to identify, attract and retain other highly qualified managerial, technical and sales and marketing personnel. Competition for these individuals is intense. The loss of the services of any of our key personnel, the inability to identify, attract or retain qualified personnel in the future or delays in hiring qualified personnel, could make it more difficult for us to manage our business and meet key objectives, such as the timely introduction of our proposed products, which would harm our business, financial condition and operating results.

Risks Relating to Our Common Stock

Because the average daily trading volume of our common stock is low, your ability to sell your shares in the secondary trading market may be limited.

Because the average daily trading volume of our common stock is low, the liquidity of our common stock may be impaired. As a result, prices for shares of our common stock may be lower than might otherwise prevail if the average daily trading volume of our common stock was higher. Our common stock began trading on the American Stock Exchange under the ticker symbol BPA at the opening of trading on October 1, 2003. Despite the trading of our common stock on the American Stock Exchange, we believe that the average daily trading volume of our common stock may be low relative to the stocks of other exchange-listed companies, which could limit your ability to sell your shares in the secondary trading market.

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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.

Our stock price may be volatile and your investment in our common stock could suffer a decline in value.

On October 1, 2003, our common stock began trading on the American Stock Exchange. The market price of our common stock may fluctuate significantly in response to a number of factors, some of which are beyond our control. These factors include:

progress of our products through the regulatory process;

results of preclinical studies and clinical trials;

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

government regulatory action affecting our products or our competitors' products in both the United States and foreign countries;

developments or disputes concerning patent or proprietary rights;

actual or anticipated fluctuations in our operating results;

changes in our financial estimates by securities analysts;

general market conditions for emerging growth and pharmaceutical companies;

broad market fluctuations; and

economic conditions in the United States or abroad.

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.

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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 31.6% 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 September 30, 2003, we had issued and outstanding 13,485,405 shares of common stock, 466,602 shares of our class C stock and outstanding options and warrants to purchase 5,713,750 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.

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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 previous private placements. The net proceeds from our sale of these shares to the selling stockholders have been and will be used for general corporate purposes, including working capital.

Table of Contents**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 private transactions. The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of September 30, 2003 as provided by the selling stockholders. In accordance with the rules of the SEC, beneficial ownership includes the shares issuable pursuant to warrants and options that are exercisable within 60 days of September 30, 2003. Shares issuable pursuant to warrants and options are considered outstanding for computing the percentage of the person holding the warrants and options but are not considered outstanding for computing the percentage of any other person.

The percentage of beneficial ownership for the following table is based on 13,485,405 shares of common stock outstanding as of September 30, 2003. 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.

Selling Stockholder	Shares Beneficially Owned Prior to the Offering			Number of Shares Being Offered	Shares Beneficially Owned After Completion of the Offering	
	Shares Subject to Options, Warrants, and Class C Special Stock	Total Shares Beneficially Owned			Number	Percentage
		Owned	Percentage			
SDS Merchant Fund, LP (1)	232,558	697,674	5.1%	697,674	0	
North Sound Legacy Fund LLC	10,465	31,395	*	31,395	0	
North Sound Legacy Institutional Fund LLC	105,814	317,442	2.3%	317,442	0	
North Sound Legacy International Ltd.	116,279	348,837	2.6%	348,837	0	
Perceptive Life Sciences Master Fund, Ltd. (2)	550,000	1,650,000	11.8%	1,650,000	0	
Joseph Edelman (3)	112,500	337,500	2.5%	337,500	0	
Multi-National Consulting Services IV, LLC	11,500	34,500	*	34,500	0	
Daniel Heller	5,750	17,250	*	17,250	0	
SCO Capital Partners LLC (4)	335,473	585,473	4.2%	585,473	0	
Paul Scharfer	149,850	316,350	2.3%	316,350	0	
Quogue Capital LLC	145,000	435,000	3.2%	435,000	0	
Orion Biomedical Fund, LP	190,999	572,996	4.2%	572,996	0	
Orion Biomedical Offshore Fund, LP	41,502	124,505	1.0%	124,505	0	
Richard Stone	10,000	30,000	*	30,000	0	
The Steven M. Oliveira 1998 Charitable Remainder Trust	116,250	348,750	2.6%	348,750	0	
Panacea Fund, LLC	75,000	225,000	1.7%	225,000	0	
Crestview Capital Fund II, LP	46,512	139,535	1.0%	139,535	0	
Richard Sheiner	4,000	12,000	*	12,000	0	
Dr. Terry L. Lazarus	4,000	12,000	*	12,000	0	
Charles Burns	4,000	12,000	*	12,000	0	
Jeffrey B. Davis	66,600	66,600	*	66,600	0	
Preston Tsao	20,000	20,000	*	20,000	0	

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**Shares Beneficially
Owned Prior to the Offering**