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PROSPECTUS SUPPLEMENT
(To Prospectus dated December 19, 2003)

Filed Pursuant to Rule 424(b)(5)
File Number 333-111360

2,200,000 Shares

DISCOVERY LABORATORIES, INC.

COMMON STOCK

Discovery Laboratories, Inc., is offering 2,200,000 shares of common stock.

Our common stock is traded on the Nasdaq SmallCap Market under the symbol “DSCO.” On March 29, 2004, the last reported sale price of our common stock on the Nasdaq SmallCap Market was $11.49.

Investing in our common stock involves risks. See “Risks Related to Our Business” set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and “Risk Factors” beginning on page S-3 of this prospectus supplement and page 6 of the accompanying prospectus for a discussion of some important risks you should consider before buying our common stock.

	Per Share	Total
Public offering price	$ 11.00	$ 24,200,000
Underwriting discount	$ 0.55	$ 1,210,000
Proceeds to Discovery Laboratories, Inc. (before expenses)	$ 10.45	$ 22,990,000

Delivery of the shares will be made on or about April 2, 2004.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities, or passed upon the accuracy or adequacy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

Bear, Stearns & Co. Inc.

The date of this prospectus supplement is March 29, 2004

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PROSPECTUS SUPPLEMENT

PROSPECTUS

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein or therein. We have not authorized anyone to provide you with information different from that contained in any of these documents. The information contained in these documents is accurate only as of the date of each document, as the case may be, regardless of the time of delivery of this prospectus supplement and accompanying prospectus or of any sale of common stock. Our business, financial condition, results of operations and prospects may change after the date set forth in each document in which the information is presented.

We are making offers to sell and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. You should not consider this prospectus supplement and the accompanying prospectus to be an offer to sell, or a solicitation of an offer to buy, shares of common stock if the person making the offer or solicitation is not qualified to do so or if it is unlawful for you to receive the offer or solicitation.

References in the prospectus supplement, the accompanying prospectus and the documents incorporated by reference to “we,” “our,” “us” and the “company” refer to Discovery Laboratories, Inc., and its subsidiaries, unless the context requires otherwise.

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a "shelf" registration statement on Form S-3 that we filed with the Securities and Exchange Commission on December 19, 2003. This prospectus supplement describes the specific details regarding this offering, including the price, the amount of common stock being offered and the risks of investing in our common stock. The accompanying prospectus provides more general information. You should read both this prospectus supplement and the accompanying prospectus together with the additional information about us described in the accompanying prospectus in the section entitled "Where You Can Find More Information."

If information contained in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on this prospectus supplement.

RECENT EVENTS

As of February 29, 2004, the Company had cash and marketable securities of approximately $24.3 million.

FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein, including in "Risk Factors," contain, "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, including statements regarding our expectations, beliefs, intentions or strategies for the future. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to:

- the inherent risks and uncertainties in developing products of the type we are developing;
- possible changes in our financial condition;
- the progress of our research and development (including the results of clinical trials being conducted by us and the risk that our lead product candidate, Surfaxin®, will not prove to be safe or useful for the treatment of certain indications);
- adequate supplies of drug substance and drug product for our clinical trials which supplies may be difficult or uneconomical to procure or manufacture;
- timely obtaining sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies;
- our ability to obtain additional required financing to fund our research programs;
- our ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with us;
- the progress of the FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; and

- the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals.

The forward-looking statements contained in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference herein or therein speak only of their respective dates. Except to the extent required by applicable laws, rules and regulations, we do not undertake any obligation or duty to publicly update or revise any forward-looking statements in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference herein or therein, whether as a result of new information, future events or otherwise.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider the following risk factors, as well as other information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus, before deciding to purchase any shares of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may become important factors that affect us. If any of these risks occur, our business could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

Risks Related to This Offering

A substantial number of shares may be sold in the market following this offering, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. Upon completion of this offering, we will have outstanding an aggregate of 46,031,873 shares of common stock, assuming no exercise of outstanding options or warrants. A substantial majority of the outstanding shares of our common stock are, and all of the shares sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act of 1933 unless these shares are purchased by affiliates. In addition, as of March 10, 2004, 6,998,582 shares of common stock are issuable upon exercise of outstanding options and warrants granted by us, which also have been registered for resale on registration statements filed with the Commission.

Our management will have broad discretion with respect to the use of the proceeds of this offering.

We have not designated the amount of net proceeds we will receive from this offering for any particular purpose. Accordingly, our management will have broad discretion as to the application of these net proceeds and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds.

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered hereby is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of $11.00 per share in this offering, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $9.95 per share in the net tangible book value of the common stock. See “Dilution” on page S-5 for a more detailed discussion of the dilution you will incur in this offering.

USE OF PROCEEDS

We expect the net proceeds from this offering of common stock to be approximately $22.8 million after deducting the estimated underwriting discount and estimated offering expenses. We will retain broad discretion over the use of the net proceeds from the sale of our common stock offered hereby. Except as described in any prospectus supplement or post effective amendment, we currently anticipate using the net proceeds from the sale of our common stock primarily for:

- the continuing research, clinical development and regulatory requirements associated with our surfactant replacement therapies, including our lead product, Surfaxin;
- investing in and supporting a long-term manufacturing strategy including further development and scale-up of our current contract manufacturer, alternative contract manufacturers and building our own manufacturing operations in order to secure additional manufacturing capabilities to meet production needs;
- investing in marketing and commercialization (including distribution) resources to execute the launch of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, if approved, and the execution of our worldwide sales and marketing strategy; and
- investing in additional general and administrative resources primarily to support our business development initiatives, financial systems and controls and management information technologies.

The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our research and development efforts, technological advances and the competitive environment for Surfaxin and its intended uses. We also might use a portion of the net proceeds to acquire or invest in complementary businesses, products and technologies. Pending the application of the net proceeds, we expect to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

DILUTION

The net tangible book value of our common stock on December 31, 2003, was approximately $24.2 million, or approximately $0.57 per share. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the aggregate number of shares of common stock outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the sale of 2,200,000 shares of common stock in this offering at an offering price of $11.00 per share, and after deducting the estimated underwriting discount and the estimated offering expenses, our net tangible book value at December 31, 2003, would have been approximately $47 million, or approximately $1.05 per share. This represents an immediate increase in the net tangible book value per share of $0.48 per share to existing shareholders and an immediate dilution of $9.95 per share to new investors purchasing shares of common stock in this offering. The following table illustrates this dilution:

Offering price per share		$11.00
Net tangible book value per share as of December 31, 2003	$0.57	
Increase per share after the offering	$0.48	
Net tangible book value per share as of December 31, 2003, after giving effect to this offering		$ 1.05
Dilution per share to new investors		$ 9.95

The foregoing table does not take into account further dilution to new investors that could occur upon the exercise of outstanding warrants and options having a per share exercise price less than the per share offering price to the public in this offering. As of December 31, 2003, there were 42,491,438 shares of common stock outstanding, which does not include:

- 5,555,322 shares of common stock issuable upon exercise of options outstanding as of December 31, 2003, at a weighted average exercise price of $3.80 per share; and
- 3,197,454 shares of common stock issuable upon exercise of warrants outstanding as of December 31, 2003, at a weighted average exercise price of $5.42.

CAPITALIZATION

The following table sets forth our audited consolidated capitalization as of December 31, 2003, on an actual basis and adjusted to give effect to the sale of 2,200,000 shares of our common stock in this offering based on the public offering price of $11.00 per share after deducting the estimated underwriting discount and estimated offering expenses.

	December 31, 2003	
	Actual	(Unaudited) As Adjusted
	(in thousands)	
Cash and marketable securities	$ 29,422	$ 52,207
Credit facility with corporate partner	2,436	2,436
Capitalized leases	1,094	1,094
Stockholders' equity:		
Common stock, $.001 par value; 60,000,000 authorized; 42,491,438 issued and outstanding; 44,691,438 as adjusted	43	43
Additional paid-in capital	122,409	145,192
Unearned portion of compensatory stock options	(2)	(2)
Deficit accumulated during development stage	(96,858)	(96,858)
Treasury stock (at cost; 167,179 shares common)	(1,289)	(1,289)
Total stockholders' equity	24,303	47,086
Total capitalization	$ 27,833	$ 50,616

The outstanding share information in the table above excludes the following:

- 5,555,322 shares of common stock issuable upon exercise of options outstanding as of December 31, 2003, at a weighted average exercise price of $3.80 per share; and
- 3,197,454 shares of common stock issuable upon exercise of warrants outstanding as of December 31, 2003, at a weighted average exercise price of $5.42.

This table should be read in conjunction with our financial statements and the notes thereto that are incorporated by reference in this prospectus supplement and the accompanying prospectus.

UNDERWRITING

We have entered into an underwriting agreement, dated as of March 29, 2004, with Bear, Stearns & Co. Inc., as representative to the several underwriters named therein. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase from us the number of shares of common stock shown opposite its name in the table below at the public offering price less the underwriting discount as set forth on the cover page of this prospectus supplement.

Underwriter	Shares
Bear, Stearns & Co. Inc.	1,980,000
Brean Murray & Co., Inc.	220,000
Total	2,200,000

The underwriters have advised us that, initially, they propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus supplement. If all the shares are not sold at the public offering price, the underwriters may change the offering price and the other selling terms. The shares are offered by the underwriters as stated herein, subject to receipt and acceptance by the underwriters and subject to the underwriters' right to reject any order in whole or in part.

The following table shows the public offering price, underwriting discount and proceeds to us from the sale of common stock.

	Per Share	Total
Public offering price	$11.00	$ 24,200,000
Underwriting discount	$ 0.55	$ 1,210,000
Proceeds to us (before expenses)	$10.45	$ 22,990,000

The expenses of the offering, other than the underwriting discount referred to above, are estimated at approximately $205,000 and are payable entirely by us.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

We and each of our executive officers and directors have agreed for a period of 30 days after the date of this prospectus supplement, subject to specified exceptions, with respect to our securities or the securities of our subsidiary, or any security convertible into, or exercisable or exchangeable for our securities or our subsidiary's securities, not to: (1) issue, offer, sell, agree to issue, offer or sell, solicit offers to purchase, grant any call option, warrant or other right to purchase, purchase any put option or other right to sell, pledge, borrow or otherwise dispose of any such securities, or make any announcement of any of the foregoing; (2) establish or increase any "put equivalent position" or liquidate or decrease any "call equivalent position" (in each case within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder); and (3) otherwise enter into any swap, derivative or other transaction or arrangement that transfers to another, in whole or in part, any economic consequence of ownership of such securities, whether or not such transaction is to be settled by delivery of such securities, other securities, cash or other consideration. The foregoing does not apply to: (1) the sale of up to an aggregate of 400,000 shares of common stock by our officers and directors; (2) sales by our officers and directors structured as pre-paid variable rate forwards; and (3) the sale of shares of common stock under this prospectus supplement and our issuance of shares of common stock: (v) in connection with the terms of joint ventures, collaborative arrangements, strategic alliances or similar transactions; (w) upon the conversion or exchange of convertible or exchangeable securities outstanding on the date hereof; (x) upon the exercise of currently outstanding options; (y) upon the exercise of currently outstanding warrants; and (z) upon the grant and exercise of options under, or the issuance and sale of shares pursuant to, employee stock option plans in effect on the date hereof, each as described in the registration statement and the accompanying prospectus.

Bear Stearns may, in its sole discretion and at any time or from time to time before the termination of the 30-day period, without notice, release all or any portion of the securities subject to lock-up agreements. Bear Stearns does not have any current intention to release any portion of the securities subject to lock-up agreements. The foregoing restrictions will not apply to the sale of common stock in this offering or the grant and exercise of options under, or the issuance and sale of shares pursuant to, employee stock option plans, and bona fide gifts of shares of common stock, provided that any such transferee agrees to be bound in writing by the restrictions set forth in the lock-up agreement.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the shares of common stock offered by this prospectus supplement and the accompanying prospectus in any jurisdiction where action for that purpose is required. The shares of common stock offered by this prospectus supplement and the accompanying prospectus may not be offered or sold, directly or indirectly, nor may this prospectus supplement, the accompanying prospectus or any other offering material or advertisements in connection with the offer and sale of any such shares of common stock be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus supplement and the accompanying prospectus come are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell or a solicitation of any offer to buy any shares of common stock offered by this prospectus supplement and the accompanying prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Our common stock trades on the Nasdaq SmallCap Market under the symbol “DSCO.” On March 29, 2004, the last reported sale price of our common stock was $11.49 per share.

A prospectus supplement and the accompanying prospectus in electronic format may be made available on the Internet site or through other online services maintained by the underwriters of this offering, or by their affiliates. Other than any prospectus supplement made available in electronic format as described above, the information on any web site containing the prospectus supplement is not part of this prospectus supplement, the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part, has not been approved or endorsed by us or the underwriters in such capacity and should not be relied on by prospective investors.

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, syndicate covering transactions and stabilizing transactions. Short sales involve syndicate sales of common stock in excess of the number of shares to be purchased by the underwriters in the offering, which creates a syndicate short position. This is also known as a “naked” short sale. Transactions to close out the covered syndicate short involve purchases of the common stock in the open market after the distribution has been completed. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of bids for or purchases of shares in the open market while the offering is in progress.

Any of these activities may have the effect of preventing or retarding a decline in the market price of the common stock. They may also cause the price of the common stock to be higher than the price that would otherwise exist in the open market in the absence of these transactions.

The underwriters may conduct these transactions on the Nasdaq SmallCap Market or otherwise. If the underwriters commence any of these transactions, the underwriters may discontinue them at any time.

The underwriters and certain of their affiliates may in the future provide investment banking and other financial and banking services to us for which they may in the future receive customary fees.

LEGAL MATTERS

The validity of the securities being registered hereunder will be passed upon for us by Dickstein Shapiro Morin & Oshinsky LLP. Certain legal matters in connection with the offering will be passed on for the underwriters by Morrison & Foerster LLP, New York, New York. Attorneys of Dickstein Shapiro Morin & Oshinsky LLP beneficially own shares of common stock and warrants to purchase additional shares of our common stock, the aggregate value of which exceeds $50,000.

EXPERTS

The consolidated financial statements appearing in our Annual Report (Form 10-K) for the year ended December 31, 2003, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of our Commission filings are also available to the public from the Commission's Website at "http://www.sec.gov." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to ir@DiscoveryLabs.com or contact John G. Cooper, our Executive Vice President, Chief Financial Officer, at our address as set forth above.

We maintain a Website at "http://www.DiscoveryLabs.com" (this is not a hyperlink, you must visit this website through an Internet browser). Our Website and the information contained therein or connected thereto are not incorporated into this prospectus supplement.

We have filed with the Commission a registration statement on Form S-3 under the Securities Act relating to the common stock we are offering by this prospectus supplement. This prospectus supplement does not contain all of the information set forth in the registration statement, the exhibits, schedules and the prospectus attached thereto. Please refer to the registration statement, the exhibits, schedules and the prospectus attached thereto for further information with respect to us and the common stock offered hereby. Statements contained in this prospectus supplement as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the registration statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the Commission, as described in the preceding paragraph.

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

SUBJECT TO COMPLETION
PRELIMINARY PROSPECTUS DATED DECEMBER 19, 2003

6,500,000 Shares

DISCOVERY LABORATORIES, INC.

COMMON STOCK

This prospectus relates to the public offering of up to 6,500,000 shares of our common stock, par value $.001 per share, which we may sell to underwriters or dealers, through agents or directly to investors.

Our common stock is quoted on the Nasdaq SmallCap Market under the trading symbol “DSCO.” On December 12, 2003, the closing sales price of our common stock as reported by Nasdaq was $9.70 per share.

AN INVESTMENT IN OUR COMMON STOCK INVOLVES SIGNIFICANT RISKS. SEE “ RISK FACTORS” BEGINNING ON PAGE 6.

In this prospectus and any prospectus supplement, unless otherwise indicated, the terms “Discovery”, “the Company”, “we”, “us” and “our” refer and relate to Discovery Laboratories, Inc., and its consolidated subsidiaries. This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using the “shelf” registration process. Under the shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings. This prospectus provides you with a general description of the securities we may offer. Each time we offer to sell securities pursuant to this registration statement and the prospectus contained herein, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in such prospectus supplement. You should read both this prospectus and any and all prospectus supplements together with additional information described under the heading, “Where You Can Find More Information.”

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 December , 2003.

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ABOUT THIS PROSPECTUS

Because this is a summary, it does not contain all the details that may be important to you. You should read this entire prospectus, including “Risk Factors,” carefully before you invest.

COMPANY SUMMARY

We are a biopharmaceutical company applying our humanized lung surfactant technology to develop potential novel respiratory therapies and products. Surfactants are substances that are produced naturally in the lungs and are essential to the lungs’ ability to absorb oxygen and to maintain proper airflow through the respiratory system. The absence or depletion of surfactants is involved in a number of respiratory diseases.

Our humanized surfactant technology produces an engineered version of natural human lung surfactant and contains a peptide, sinapultide, that was designed to precisely mimic the essential attributes of human lung surfactant protein B (SP-B). We believe that our proprietary surfactant technology is the only late stage surfactant technology presently available to potentially treat a broad range of respiratory diseases including Respiratory Distress Syndrome in adults and infants, asthma, chronic obstructive pulmonary disease (often referred to as COPD, which is a chronic condition of the lung that prevents enough oxygen from reaching the blood), Acute Lung Injury (often referred to as ALI), and upper airway disorders such as sinusitis (infection of the sinuses) and sleep apnea.

Surfaxin®, our lead product, is being developed initially for critical care patients with life-threatening respiratory disorders where there are few, if any, approved therapies. We recently completed and announced successful top-line results from two Phase 3 clinical trials of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants. We are conducting further evaluation of secondary endpoints and safety parameters and are preparing to file a new drug application (NDA) with the United States Food and Drug Administration and other regulatory authorities throughout the world. Surfaxin is also currently in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults and a Phase 3 and Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants.

Aerosolized formulations of our humanized surfactant are presently being developed to potentially treat hospitalized patients suffering from respiratory diseases. We recently initiated a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant delivered as an inhaleable aerosol for the treatment of asthma. In addition, we believe that scientific rationale supports the development of aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury, chronic obstructive pulmonary disorder (COPD), sinusitis sleep apnea and otitis media (inner ear infection).

We are presently developing a dedicated sales and marketing capability through a collaboration with Quintiles Transnational Corp. to commercialize Surfaxin for neonatal indications in the United States. We also have entered into a strategic alliance with Laboratorios del Dr. Esteve to commercialize Surfaxin in Europe and Latin America. We intend to establish additional strategic alliances, where appropriate, for the development and commercialization of our products in other indications and markets.

SURFACTANT TECHNOLOGY

Surfactants are protein and lipid (fat) compositions that are produced naturally in the lungs and are critical to all air-breathing mammals. They cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways which lead to the alveoli. Surfactants facilitate respiration by continually modifying the surface tension of the fluid normally present within the alveoli that line the inside of the lungs. In the absence of sufficient surfactant or should the surfactant degrade, these air sacs tend to collapse, and, as a result, the lungs do not absorb sufficient oxygen. In addition to lowering aveolar surface-tension, surfactants play other important

roles in human respiration which include lowering the surface tension of the conducting airways and maintaining airflow and airway patency (keeping the airways open and expanded). Human surfactants include four known surfactant proteins, A, B, C and D. It has been established, through numerous studies, that surfactant protein B (SP-B) is essential for respiratory function.

Presently, the FDA has approved surfactants as replacement therapy only for Respiratory Distress Syndrome in premature infants, a condition in which infants are born with an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Though they are clinically effective, they have drawbacks and cannot readily be scaled or developed to treat broader populations for Respiratory Distress Syndrome in premature infants and other respiratory diseases. There is presently only one approved synthetic surfactant available, however, this product does not contain surfactant proteins, is not widely used and is not actively marketed by its manufacturer.

Our humanized surfactant product candidates, including Surfaxin, are engineered versions of natural human lung surfactant and contain a humanized peptide, sinapultide. Sinapultide is a 21 amino acid protein-like substance that is designed to precisely mimic the essential attributes of human surfactant protein B (SP-B). We believe that our engineered humanized surfactant can be manufactured less expensively than the animal-derived surfactants, in sufficient quantities, in more exact and consistent pharmaceutical grade quality, and has little or no potential to cause adverse immunological responses in young and older adults, all important attributes for our products to potentially meet significant unmet medical needs. Our products also have the ability to be more precisely formulated, such as in the form of aerosolized liquids or dry powders, to address various medical indications. In addition, we believe that our engineered humanized surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient's lungs and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease").

Respiratory Distress Syndrome in Premature Infants

Respiratory Distress Syndrome is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. Premature infants born prior to 32 weeks gestation have not fully developed a natural lung surfactant and therefore need treatment to sustain life. This condition often results in the need for mechanical ventilation.

During 2003, we completed a pivotal Phase 3 clinical trial and a supportive Phase 3 clinical trial of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants. We intend to use the results from these trials to form the basis for an NDA and regulatory applications for approval in the rest of the world.

Our pivotal, multinational landmark Phase 3 trial achieved positive primary endpoint results and concluded enrollment in December 2003. The independent Data Safety Monitoring Board (DSMB) for this trial informed the study's Steering Committee that Surfaxin had achieved statistical significance in its co-primary endpoints versus Exosurf® (a non-protein containing synthetic surfactant). Survanta®, a cow-derived surfactant, served as a reference arm in the trial.

Earlier this year, we concluded our successful supportive, multinational Phase 3 clinical trial comparing Surfaxin to a certain porcine (pig) derived surfactant for the treatment of Respiratory Distress Syndrome in premature infants.

RDS in premature infants affects over two million infants annually worldwide. Due to limitations associated with the animal-derived surfactant products that are currently approved to treat Respiratory Distress Syndrome in premature infants, therapy is mainly limited to those born in the United States and Western Europe. There are hundreds of thousands of premature babies born in the world each year who need, but do not receive, effective surfactant replacement therapy.

The FDA has granted us Orphan Drug Designation for Surfaxin for Respiratory Distress Syndrome. Orphan drugs are pharmaceutical products that are intended to treat diseases affecting fewer than 200,000 patients in the United States. The Office of Orphan Product Development of the FDA grants certain advantages to the sponsors of orphan drugs including, but not limited to, seven years of market exclusivity upon approval of the drug, certain tax incentives for clinical research and grants to fund testing of the drug. We are also seeking Orphan Product designation from the European Medicines Evaluation Agency (the European Union's regulatory approval agency that is similar to the FDA) for Surfaxin for indications of Respiratory Distress Syndrome in premature infants.

Acute Respiratory Distress Syndrome in Adults

Acute Respiratory Distress Syndrome (often referred to as ARDS) is a life-threatening disorder for which no approved therapies exist anywhere in the world. It is characterized by an excess of fluid in the lungs and decreased oxygen levels in the patient. One prominent characteristic of this disorder is the destruction of surfactants naturally present in lung tissue. The conditions are caused by illnesses including pneumonia and septic shock (a toxic condition caused by infection) and events such as smoke inhalation, near drowning, industrial accidents and other traumas.

We are presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of Surfaxin for adults with Acute Respiratory Distress Syndrome. Approximately 110 patients will receive high concentrations of Surfaxin via our proprietary lavage technique that administers the drug sequentially through a tube, called a bronchoscope. The procedure is intended to cleanse and remove inflammatory substances and debris from the lungs, while leaving amounts of Surfaxin behind to help re-establish the lungs' capacity to absorb oxygen. The objective is to restore functional surfactant levels and to allow critically ill patients to be removed from mechanical ventilation.

We have completed Part A of this Phase 2 trial, a dose escalation safety and tolerability study in 22 patients in four groups (of up to six patients per group). In consultation with the trial's Independent Safety Review Committee, comprised of three prominent pulmonologists, we determined that the Part A portion of the trial procedure is generally safe and tolerable and that it was appropriate for us to proceed onto the larger safety and efficacy portion of the trial.

The last part of this Phase 2 trial, Part B, is designed to evaluate safety and efficacy of Surfaxin in direct comparison to the current standard of care and will be conducted at approximately 40 centers throughout the United States. The primary endpoint of Part B is to determine the incidence rate of patients surviving and off mechanical ventilation at the end of day 28 with one of the key secondary endpoints being mortality. We have recently entered into a manufacturing and technology transfer agreement with a new contract manufacturer for drug product for this trial. See "Risk Factors-If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products."

The current standard of care for Acute Respiratory Distress Syndrome includes placing patients on mechanical ventilators in intensive care units at a cost approximately equal to $8,500 per day, typically for an average of 21 to 28 days. There are estimated to be between 150,000 and 250,000 adults per year in the United States suffering from Acute Respiratory Distress Syndrome with similar numbers afflicted in Europe. Because there are no approved treatments for these diseases, the mortality rate can range from 35% to 50%.

The FDA has granted us Fast-Track Approval Status and Orphan Drug Designation for Surfaxin for the treatment of Acute Respiratory Distress Syndrome for adults. The European Medicines Evaluation Agency has granted us Orphan Product designation for Surfaxin for the treatment of Acute Lung Injury in adults (which in this circumstance encompasses Acute Respiratory Distress Syndrome). We were awarded a $1 million Fast-Track Small Business Innovative Research Grant by the National Institutes of Health to develop Surfaxin for the treatment of Acute Respiratory Distress Syndrome and Acute Lung Injury in adults.

Meconium Aspiration Syndrome in Full-Term Infants

Meconium Aspiration Syndrome (often referred to as MAS) is a condition in which full-term infants are born with meconium in their lungs that depletes the natural surfactant in their lungs.

Meconium is a baby's first bowel movement in its mother's womb and, when inhaled, Meconium Aspiration Syndrome can occur. Meconium Aspiration Syndrome can be life-threatening as a result of the failure of the lungs to absorb sufficient oxygen. This condition results in the infant's need for mechanical ventilation.

Surfaxin is being evaluated in a Phase 3 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants. To our knowledge, Surfaxin is the only product being developed worldwide to treat this syndrome. The trial is designed for the enrollment of up to 200 infants at medical centers throughout the United States to compare our proprietary Surfaxin lavage to the current standard of care. Enrollment has been slower than expected and resources have been reallocated from the MAS program to the RDS program to facilitate the completion of the follow-up phase and preparation and filing of the NDA for that indication.

We also have initiated a Phase 2 clinical trial of our proprietary Surfaxin lavage in up to 60 full-term infants for use as a prophylactic or in the early treatment for patients who are at risk for Meconium Aspiration Syndrome but have not shown symptoms of compromised respiratory function. We believe an effective and affordable surfactant prophylactic therapy could significantly lower the risk to meconium-stained infants of chronic respiratory conditions and reduce the need for costly mechanical ventilation.

There are presently no drug therapies approved for the treatment of Meconium Aspiration Syndrome in full-term infants. An estimated 60,000 infants are born in the United States and Europe that require treatment for MAS, however, a significantly greater number of infants are born worldwide each year at risk for MAS. The FDA has granted us Fast-Track Approval Status and Orphan Drug Designation for Surfaxin for the treatment of Meconium Aspiration Syndrome in full-term infants. We have also received Orphan Product designation of Surfaxin for the treatment of Meconium Aspiration Syndrome from the European Medicines Evaluation Agency.

Our Aerosolized Humanized Surfactants for Respiratory Therapy

Many respiratory diseases are associated with an inflammatory event that causes surfactant dysfunction and a loss of patency of the conducting airways. Scientific data support the premise that the therapeutic use of surfactants in aerosol form has the ability to reestablish airway patency, improve pulmonary mechanics and act as an anti-inflammatory. Surfactant normally prevents moisture from accumulating in the airways' most narrow sections and thereby maintains the patency of the conducting airways.

We are currently developing aerosolized formulations of our humanized surfactant to potentially treat patients who could benefit from surfactant-based therapy to improve lung function and maintain proper airflow through the respiratory system. Our aerosol development program is initially focused on surfactant-based therapy for hospitalized patients suffering from severe acute asthma or Acute Lung Injury. For asthma, we recently initiated a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant delivered as an inhaleable aerosol. In addition, we believe that scientific rationale supports the development of aerosolized formulations of our humanized surfactant to potentially treat COPD, sinusitis, sleep apnea and otitis media (inner ear infection).

We are presently working with various aerosol devices towards achieving the following important development objectives:

— Full retention of the surface-tension lowering properties of a functioning surfactant necessary to restore lung function and maintain patency of the conducting airways;

— Full retention of the surfactant composition of the lungs upon aerosolization;

— Drug particle size suitable for deposition in the deep-lungs;

- Delivery rates to achieve therapeutic dosages in a reasonable time period; and
- Reproducible aerosol output and minimal waste of surfactant dose.

Asthma

We recently initiated a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from asthma. This single-blind, placebo-controlled, randomized, dose-escalation study, is being conducted at a pulmonary research facility and is designed to enroll 6 healthy subjects and up to 12 mild-persistent asthmatic patients. The primary study objective is to assess preliminary safety and tolerability as well as to establish the deposition characteristics of this aerosolized formulation of our surfactant technology.

Asthma is a common disease characterized by sudden constriction and inflammation of the lungs. Constriction of the upper airway system is caused by a tightening of airway muscles, while inflammation is a swelling of the airways usually due to an allergic reaction due to an airborne irritant. Both of these events cause airways to narrow and may result in wheezing, shortness of breath and chest tightness. Several studies have shown that surfactant damage and dysfunction is a significant component of asthma—airway obstruction occurs when there is a surfactant dysfunction in the airways of the deep lung of the type that develops during an asthma attack. We believe that surfactant replacement therapy has the potential to relieve the obstruction in the airways associated with asthma.

According to information provided by the American Lung Association, asthma afflicts approximately 20.3 million people in the United States and its incidence rate is rising. Asthma is a chronic disease; prevalent in people of all ages and an estimated 12 million people have experienced an asthma attack within the past year. In the United States alone, there are roughly 1 million hospital outpatient visits, approximately 1.8 million emergency room visits and 9.3 million physician visits each year due to asthma. Asthma ranks within the top 10 prevalent activity-limiting health conditions costing $14 billion in United States healthcare costs annually.

Asthma may require life-long therapy to prevent or treat episodes. Ten percent of patients are considered severe asthmatics and require moderate to high doses of drugs. Currently available medications to treat and control asthma include inhaled and oral steroids and bronchodilators. Bronchodilators cannot be used to control severe episodes or chronic, severe asthma. Steroidal medications are used to address these conditions, however, steroids can cause serious side effects when used for prolonged periods. As a result, steroid use is typically limited to severe asthmatic episodes and chronic, severe asthma.

Several small scientific studies report that patients suffering from a severe, acute asthma attack were relieved when they inhaled aerosolized surfactant. We believe that supplying surfactant as an aerosol spray may be a simple and gentle way of relieving airway obstruction thereby augmenting currently available conventional asthma therapies and leading to a more rapid improvement in asthmatic symptoms.

Acute Lung Injury

Acute Lung Injury is associated with conditions that either directly or indirectly injure the air sacs of the lung, the alveoli. Acute Lung Injury is a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs' surfactant layer. The most serious manifestation of Acute Lung Injury is Acute Respiratory Distress Syndrome.

Among the causes of Acute Lung Injury are complications typically associated with certain major surgeries, mechanical ventilator induced lung injury (often referred to as VILI), smoke inhalation, pneumonia and sepsis. There are an estimated 1 million patients at risk in the United States for Acute Lung Injury annually and there are no currently-approved therapies.

We believe that our proprietary humanized aerosol surfactant may be effective as a preventive measure for patients at risk for Acute Lung Injury. This prophylactic approach may result in fewer patients requiring costly intensive care therapy and shorter periods of therapy—thus offering cost savings in the hospital setting.

CORPORATE INFORMATION

Surfaxin® is our trademark. This prospectus also includes product names, trademarks and trade names of other companies, which names are the exclusive property of the holders thereof.

Our executive offices are located at 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901. Our telephone number is (215) 340-4699 and our facsimile number is (215) 340-3940.

RISK FACTORS

An investment in our common stock involves significant risks. You should carefully consider the risks described below and other information, including our financial statements and related notes previously included in our periodic reports filed with the SEC. If any of the factors or conditions summarized in the following risks actually occur, our business prospects, financial condition and results of operations could be materially harmed, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are those that we currently believe may materially affect us. Additional risks and uncertainties of which we are unaware or which we currently deem immaterial also may become important factors that affect us.

Because we are a development stage company, we may not successfully develop and market our products, and even if we do, we may not generate enough revenue or become profitable.

We are a developmental stage biopharmaceutical company. Therefore, you must evaluate us in light of the uncertainties and complexities present in such companies. We currently have no products approved for marketing and sale and are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of these products. Our long-term viability will be impaired if we are unable to obtain regulatory approval for, or successfully market, our product candidates.

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of September 30, 2003, we have incurred a deficit accumulated during the development stage of approximately $88.2 million, and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

Our technology platform is based solely on our proprietary humanized, engineered surfactant technology and only our lead product candidate, Surfaxin, has been subject to clinical studies. Our ongoing clinical trials for Surfaxin and other product candidates based upon our Surfactant Replacement Technologies may be delayed, or fail, which will harm our business.

Our humanized, engineered surfactant platform technology is based on the scientific rationale for surfactant replacement therapy to treat life threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this platform technology. Recently we completed and announced top-line results from a pivotal Phase 3 clinical trial and supportive Phase 3 clinical trial with our lead product, Surfaxin, for the treatment of Respiratory Distress Syndrome in premature infants. In addition, we are conducting a Phase 2 clinical trial for Acute Respiratory Distress syndrome in adults and a Phase 3 and Phase 2 clinical trial

for Meconium Aspiration Syndrome in full-term infants. We recently initiated a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from asthma.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility criteria for the study;
- the existence of competing clinical trials; and
- the existence of alternative available products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

We will need additional capital, and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution.

We will need substantial additional funding to conduct our presently planned research and product development activities. Based on our current operating plan, we believe that our currently available financial resources will be adequate to satisfy our capital needs into 2005. Our future capital requirements will depend on a number of factors that are uncertain, including the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process, among others. We will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may also continue to seek additional funding through capital lease transactions. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

We have not entered into arrangements to obtain any additional financing, except for the credit facility with PharmaBio Development Inc., a subsidiary of Quintiles, and our capital equipment lease financing arrangement with General Electric Capital Corporation. Any additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations.

Furthermore, we could cease to qualify for listing of our securities on the NASDAQ SmallCap Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See "Risk Factors—The market price of our stock may be adversely affected by market volatility."

The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.

In order to sell our products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation by the FDA and comparable agencies in foreign countries that the manufacturer maintains good laboratory and manufacturing practices during testing and manufacturing. Although we are involved in certain late-stage clinical trials, pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated by clinical trials of drug products, the FDA may not approve an NDA filed by a pharmaceutical or biotechnology company for such drug product.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not reach agreement with the FDA and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects that are common to this class of drug such as a decrease in the oxygen level of the blood upon administration.

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least 2005, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for our humanized surfactant-based therapy, Meconium Aspiration Syndrome in full-term infants and Acute Respiratory Distress Syndrome in adults, have been granted designation as “fast-track” products under provisions of the Food and Drug Administration Modernization Act of 1997. The FDA has also granted us Orphan Drug Designation for three of our intended indications for Surfaxin, Acute Respiratory Distress Syndrome in adults and Respiratory Distress Syndrome in infants, and Meconium Aspiration Syndrome in full-term infants. To support our development of Surfaxin for the treatment of Meconium Aspiration Syndrome, the FDA has awarded us an Orphan Products Development Grant. Fast-Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast-Track Status provisions are designed to expedite the FDA’s review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years. Our products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

The FDA and comparable foreign agencies could withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make

product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve our products, we will not be able to market our products.

In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product and competitor's drug product, which may not be readily available.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We rely on third party contract manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical trials of our products. We recently transferred our manufacturing capabilities from our single validated clinical manufacturing facility, owned and operated by Akorn, Inc., to a new contract manufacturer, Laureate Pharma, with the objective of producing appropriate clinical grade material of our drug substance that meet the standards for use in our ongoing clinical studies. Laureate Pharma may not be able to produce Surfaxin to appropriate standards for use in clinical studies. A failure by Laureate to do so may delay or impair our ability to obtain regulatory approval for Surfaxin. See also "Risk Factors—If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products."

If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products.

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of our products. Presently, we have no validated clinical manufacturing facility to produce appropriate clinical grade material of our drug substance for use in our ongoing clinical studies.

Laureate Pharma or other outside manufacturers may not be able to (i) produce our drug substance to appropriate standards for use in clinical studies, (ii) perform under the definitive manufacturing agreement once such agreements are executed, if at all, or (iii) remain in the contract manufacturing business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We may in the future elect to manufacture some of our products on our own. Although we own certain specialized manufacturing equipment, are considering an investment in additional manufacturing equipment and employ certain manufacturing managerial personnel, we do not presently maintain a complete manufacturing facility or manufacturing department and we do not anticipate manufacturing on our own any of our products during the next 12 months. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

The FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with good manufacturing practices (GMPs) or similar requirements that the FDA or corresponding foreign regulators establish. Manufacturing or quality control problems could occur at the contract manufacturers causing product

production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's current GMP requirements necessary to continue manufacturing our drug substance. If our third-party foreign or domestic suppliers or manufacturers of our products, or, if we decide to manufacture our products on our own, we, fail to comply with GMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products.

Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

Our strategy for the completion of the required development and clinical testing of our products and for the manufacturing, marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. We have a collaboration arrangement with Esteve for Surfaxin covering all of Europe and Latin America. Esteve will be responsible for the marketing of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for commercialization of Surfaxin in Europe for the Acute Lung Injury/Acute Respiratory Distress Syndrome indications. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to European Medicines Evaluation Agency filings.

We have entered into an exclusive collaboration arrangement in the United States with Quintiles, and its affiliate, PharmaBio, to commercialize, sell and market Surfaxin in the United States for indications of Respiratory Distress Syndrome and Meconium Aspiration Syndrome. As part of our collaboration with Quintiles, Quintiles will build a sales force solely dedicated to the sale of Surfaxin upon the approval of a New Drug Application for either of the two indications. If Quintiles and we fail to devote appropriate resources to commercialize, sell and market Surfaxin, sales of Surfaxin could be reduced. As part of the collaboration, PharmaBio is obligated to provide us with certain financial assistance in connection with the commercialization of Surfaxin, including, but not limited to, a secured, revolving credit facility for at least $8.5 million which may be increased to $10 million. A failure by us to repay amounts outstanding under the credit facility would have a material adverse effect on us. To obtain the benefits of such financing, we are obligated to meet certain development and performance milestones. The failure by us to meet the milestones or other terms and conditions of the financing leading to PharmaBio's termination thereof or the failure by PharmaBio to fulfill its obligation to partially fund the commercialization of Surfaxin, may affect our ability to successfully market Surfaxin.

If Esteve, Quintiles, PharmaBio or we breach or terminate the agreements that make up such collaboration arrangements or Esteve, Quintiles or PharmaBio otherwise fail to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their respective obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin which Esteve, Quintiles and/or PharmaBio have agreed to assist in commercializing. Accordingly, we may need to enter into additional collaboration agreements and our success, particularly outside of the United States, may depend upon obtaining additional collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner

and would have a material adverse effect on the commercialization of Surfaxin. See “Risk Factors—Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales.”

If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products.

We seek patent protection for our drug candidates so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. 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 on our ability and that of parties from whom we license technology to:

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us.

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the United States Patent and Trademark Office or foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson, Inc., and Ortho Pharmaceutical Corporation which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2020 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also “Risk Factors—If we cannot meet requirements under our license agreements, we could lose the rights to our products.”

Intellectual property rights of third parties could limit our ability to market our products.

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The United States Patent and Trademark Office keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

If we cannot meet requirements under our license agreements, we could lose the rights to our products.

We depend on licensing arrangements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Johnson & Johnson and Ortho Pharmaceutical. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing arrangements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

In addition, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We rely on confidentiality agreements that could be breached and may be difficult to enforce.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- they will breach these agreements;
- any agreements we obtain will not provide adequate remedies for this type of breach or that our trade secrets or proprietary know-how will otherwise become known or competitors will independently develop similar technology; and
- our competitors will independently discover our proprietary information and trade secrets.

Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales.

We do not have marketing, sales or distribution experience or marketing or sales personnel. As a result, we will depend on our collaboration with Quintiles for the marketing and sales of Surfaxin for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants in the United States and with Esteve for the marketing and sales of Surfaxin for the treatment of Respiratory Distress Syndrome, Meconium Aspiration Syndrome and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in all of Europe and Latin America. See "Risk Factors-Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products." If we do not develop a marketing and sales force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products.

The sales and marketing of Surfaxin for indications of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in the relevant territories depends, in part, on Quintiles' and Esteve's performance of their contractual obligations. The failure of either party to do so would have a material adverse effect on the sales and marketing of Surfaxin. We may not succeed in entering into any satisfactory third party arrangements for the marketing and sale of our remaining products. In addition, we may not succeed in developing marketing and sales capabilities, our commercial launch of certain products may be delayed until we establish marketing and sales capabilities or we may not have sufficient resources to do so. If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties, either in a timely manner, it will adversely affect sales of our products.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have an employment agreement with Dr. Capetola that expires on December 31, 2005. We also have employment agreements with other key personnel with termination dates from 2003 through 2005. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers.

While we attempt to provide competitive compensation packages to attract and retain key personnel, some of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies intensely in many ways. We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

- developing products;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals or products; and
- manufacturing and marketing products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

Presently, there are no approved drugs that are specifically indicated for Meconium Aspiration Syndrome in full-term infants or Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Current therapy consists of general supportive care and mechanical ventilation.

Four products, three that are animal-derived and one that is a synthetic, are specifically approved for the treatment of Respiratory Distress Syndrome in premature infants. Exosurf® is synthetic and is marketed by GlaxoSmithKline, plc, outside the United States and contains only phospholipids (the fats normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. Curosurf® is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta®, marketed by the Ross division of Abbott Laboratories, Inc., is an extract of bovine lung that contains the cow version of surfactant protein C. Forest Laboratories, Inc., markets its calf lung surfactant, Infasurf® in the United States for the treatment of Respiratory Distress Syndrome in premature infants. Although none of the four approved surfactants for Respiratory Distress Syndrome in premature infants is approved for Acute Lung Injury or Acute Respiratory Distress Syndrome in adults, which are significantly larger markets, there are a significant number of other potential therapies in development for the treatment of Acute Lung Injury/Acute Respiratory Distress Syndrome that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered humanized surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products approved for the treatment of Respiratory Distress Syndrome in premature infants and will have no capability of transmitting the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”) or causing adverse immunological responses in young and older adults.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will

also compete with us in recruiting highly qualified scientific personnel. We expect that therapeutic developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

If product liability claims are brought against us, it may result in reduced demand for our products or damages that exceed our insurance coverage.

The clinical testing of, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to $10,000,000 per occurrence and $10,000,000 in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock.

We expect to face uncertainty over reimbursement and healthcare reform.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third party payors, which include government health administration authorities, managed care providers and private health insurers. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interest.

As of September 30, 2003, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 15% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

— announcements of the results of clinical trials by us or our competitors;

— adverse reactions to products;

- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the United States or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks described in this "Management's Discussion and Analysis—Risk Factors."

Our common stock is listed for quotation on the NASDAQ SmallCap Market. Year to date through December 12, 2003, the price of our common stock has ranged from $1.32 to $10.27. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. Year to date through December 12, 2003, the average daily trading volume in our common stock was approximately 395,000 shares and the average number of transactions per day was approximately 697. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the SmallCap Market. If the common stock were no longer listed on the SmallCap Market, investors might only be able to trade in the over-the-counter market in the Pink Sheets® (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if meritless or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital.

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of November 30, 2003, we had 42,378,483 shares of common stock outstanding. In addition, as of November 30, 2003, up to approximately 8,798,000 shares of our common stock were issuable upon exercise of outstanding options and warrants.

Holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our common stock.

Provisions of our Certificate of Incorporation and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval, including large blocks of preferred stock. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock.

FORWARD-LOOKING STATEMENTS

The statements set forth under the captions “Company Summary” and elsewhere in this prospectus, including in “Risk Factors,” and those incorporated by reference herein which are not historical constitute “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, including statements regarding the expectations, beliefs, intentions or strategies for the future. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: the inherent risks and uncertainties in developing products of the type we are developing; possible changes in our financial condition; the progress of our research and development (including the results of clinical trials being conducted by us and the risk that our lead product candidate, Surfaxin®, will not prove to be safe or useful for the treatment of certain indications); clinical trials require adequate supplies of drug substance and drug product which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research programs; our ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with us; the progress of the FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; and the additional costs and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals.

Except to the extent required by applicable laws, rules and regulations, we do not undertake any obligation or duty to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

DESCRIPTION OF COMMON STOCK

General

This prospectus summarizes the general terms of our common stock. For a more detailed description of the common stock, you should read the applicable provisions of Delaware law and our restated certificate of incorporation and bylaws. Under our restated certificate of incorporation, the total number of shares of all classes of stock that we have authority to issue is 65,000,000, consisting of 60,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

This description of our common stock is a summary. You should keep in mind, however, that it is our restated certificate of incorporation and our bylaws, and not this summary, which defines any rights you may acquire as a shareholder. There may be other provisions in such documents which are also important to you. You should read such documents for a full description of the terms of our capital stock.

Subject to any preferential rights of any preferred stock created by our board of directors, as a holder of our common stock you are entitled to such dividends as our board of directors may declare from time to time out of funds that we can legally use to pay dividends. The holders of common stock possess exclusive voting rights, except to the extent our board of directors specifies voting power for any preferred stock that, in the future, may be issued.

As a holder of our common stock, you are entitled to one vote for each share of common stock and do not have any right to cumulate votes in the election of directors. In the event of our liquidation, dissolution or winding-up, you will be entitled to receive on a proportionate basis any assets remaining after provision for payment of creditors and after payment of any liquidation preferences to holders of preferred stock. Holders of our common stock have no preemptive rights and no conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. All the outstanding shares of common stock are, and the shares offered by this prospectus, when issued and paid for, will be, validly issued, fully paid and nonassessable. Our common stock is quoted on Nasdaq under the symbol “DSCO”.

Preferred Stock

We currently have no outstanding shares of preferred stock. Under our certificate of incorporation, our board of directors is authorized to issue shares of our preferred stock from time to time, in one or more classes or series, without stockholder approval. Prior to the issuance of shares of each series, the board of directors is required by the General Corporation Law of the State of Delaware and our certificate of incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. Any exercise of our Board of Directors of its rights to do so may effect the rights and entitlements of the holders of our common stock as set forth above.

Anti-Takeover Provisions

As a corporation organized under the laws of the State of Delaware, we are subject to Section 203 of the Delaware General Corporation Law, which restricts our ability to enter into business combinations with an interested stockholder or a stockholder owning 15% or more of our outstanding voting stock, or that stockholder’s affiliates or associates, for a period of three years. These restrictions do not apply if:

- prior to becoming an interested stockholder, our board of directors approves either the business combination or the transaction in which the stockholder becomes an interested stockholder;
- upon consummation of the transaction in which the stockholder becomes an interested stockholder, the interested stockholder owns at least 85% of our voting stock outstanding at the time the transaction commenced, subject to exceptions; or

— on or after the date a stockholder becomes an interested stockholder, the business combination is both approved by our board of directors and authorized at an annual or special meeting of our stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Number of Directors; Removal

The bylaws provide that the Board of Directors shall consist of at least three directors and may consist of such larger number as may be determined, from time-to-time, by the Board of Directors. The bylaws provide that directors may be removed with or without cause by the affirmative vote of holders of a majority of the total voting power of all outstanding securities.

This provision and the Board of Director's right to issue shares of our preferred stock from time to time, in one or more classes or series without stockholder approval are intended to enhance the likelihood of continuity and stability in the composition of the policies formulated by our Board of Directors. These provisions are also intended to discourage some tactics that may be used in proxy fights.

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock is Continental Stock Transfer & Trust Company.

USE OF PROCEEDS

We will retain broad discretion over the use of the net proceeds from the sale of our common stock offered hereby. Except as described in any prospectus supplement or post effective amendment, we currently anticipate using the net proceeds from the sale of our common stock hereby primarily for clinical development of Surfaxin, as well as commercialization activities and general corporate and administrative purposes, including working capital and research and development expenses. In addition, we may use some of the net proceeds to hire additional personnel or to pursue internal manufacturing capabilities. The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our research and development efforts, technological advances and the competitive environment for Surfaxin and its intended uses. We might also use a portion of the net proceeds to acquire or invest in complementary businesses, products and technologies. Pending the application of the net proceeds, we expect to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

DILUTION

The net tangible book value of our common stock on September 30, 2003, was approximately $31.6 million, or approximately $0.75 per share. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the aggregate number of shares of common stock outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the sale of 6,500,000 shares of common stock in this offering at an assumed public offering price of $9.58 per share, and after deducting estimated underwriting discounts and commissions and offering expenses, our net tangible book value at September 30, 2003 would have been approximately $90.1 million, or approximately $1.85 per share. This represents an immediate dilution of $7.73 per share to new investors purchasing shares of common stock in this offering. The following table illustrates this dilution:

Assumed public offering price per share	$9.58
Net tangible book value per share as of September 30, 2003	$0.75
Increase per share attributable to new investors	1.10
Net tangible book value per share as of September 30, 2003 after giving effect to this offering	1.85
Dilution per share to new investors	$7.73

The foregoing table does not take into account further dilution to new investors that could occur upon the exercise of outstanding warrants and options having a per share exercise price less than the per share offering price to the public in this offering. As of September 30, 2003, there were 42,080,094 shares of common stock outstanding, which does not include:

- 5,678,323 shares of common stock issuable upon exercise of options outstanding as of September 30, 2003, at a weighted average exercise price of $3.68 per share;
- 3,347,552 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2003 at a weighted average exercise price of $5.41;
- 159,509 shares of common stock available for future grant under our Amended and Restated 1998 Employee Stock Option Plan and 150,000 shares of common stock available for future issuance under our 401(k) Plan, all as of September 30, 2003.

The above table does not reflect the expected reported loss for the last quarter of fiscal quarter 2003, which would increase the dilution per share.

PLAN OF DISTRIBUTION

We may sell the shares being offered by us in this prospectus pursuant to underwritten public offerings, negotiated transactions, block trades or any combination of such methods. We may sell the shares to or through underwriters, dealers, agents or directly to one or more purchasers. We and our agents reserve the right to accept and to reject in whole or in part any proposed purchase of shares. A prospectus supplement or post effective amendment, which we will file each time we effect an offering of any shares, will provide the names of any underwriters, dealers or agents, if any, involved in the sale of such shares, and any applicable fees, commissions, or discounts to which such persons shall be entitled to in connection with such offering.

We and our agents, dealers and underwriters, as applicable, may sell the shares being offered by us in this prospectus from time to time in one or more transactions as follows:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

We may determine the price or other terms of the shares offered under this prospectus by use of an electronic auction. We will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the underwriters' obligations in the applicable prospectus supplement or amendment.

We may solicit directly offers to purchase shares. We may also designate agents from time to time to solicit offers to purchase shares. Any agent that we designate, who may be deemed to be an underwriter as that term is

defined in the Securities Act, may then resell such shares to the public at varying prices to be determined by such agent at the time of resale. We may engage in at the market offerings of our common stock. An at the market offering is an offering of our common stock at other than a fixed price to or through a market maker. Under Rule 415(a)(4) promulgated under the Securities Act, the total value of at the market offerings made under this prospectus may not exceed 10% of the aggregate market value of our common stock held by non-affiliates. We shall name any underwriter that we engage for an at the market offering in a post-effective amendment to the registration statement containing this prospectus. We shall also describe any additional details of our arrangement with such underwriter, including commissions or fees paid, or discounts offered, by us and whether such underwriter is acting as principal or agent, in the related prospectus supplement. If we use underwriters to sell shares, we will enter into an underwriting agreement with the underwriters at the time of the sale to them, which agreement shall be filed as an exhibit to the related prospectus supplement. Underwriters may also receive commissions from purchasers of the shares.

Underwriters may also use dealers to sell shares. In such an event, the dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents.

Underwriters, dealers, agents and other persons may be entitled, under agreements that may be entered into with us, to indemnification by us against certain civil liabilities, including liabilities under the Securities Act or to contribution with respect to payments which they may be required to make in respect of such liabilities. Underwriters and agents may engage in transactions with, or perform services for, us in the ordinary course of business. If so indicated in the applicable prospectus supplement, we may authorize underwriters, dealers or other persons to solicit offers by certain institutions to purchase the shares offered by us under this prospectus pursuant to contracts providing for payment and delivery on a future date or dates. The obligations of any purchaser under these contracts will be subject only to those conditions described in the applicable prospectus supplement, and the prospectus supplement will set forth the price to be paid for shares pursuant to those contracts and the commissions payable for solicitation of the contracts.

Any underwriter may engage in over-allotment, stabilizing and syndicate short covering transactions and penalty bids in accordance with Regulation M of the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions involve bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate short covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the underwriters to reclaim selling concessions from dealers when the shares originally sold by such dealers are purchased in covering transactions to cover syndicate short positions. These transactions may cause the price of the shares sold in an offering to be higher than it would otherwise be. These transactions, if commenced, may be discontinued by the underwriters at any time.

Each issuance of shares offered under this prospectus will be a new issue of our common stock, which is currently listed on the Nasdaq SmallCap Market. Any shares of our common stock sold pursuant to a prospectus supplement will be listed on the Nasdaq SmallCap Market or on the exchange on which the stock offered is then listed, subject (if applicable) to official notice of issuance. Any underwriters to whom we sell shares for public offering and sale may make a market in the shares that they purchase, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

The anticipated date of delivery of the shares offered hereby will be set forth in the applicable prospectus supplement relating to each offering.

In order to comply with certain state securities laws, if applicable, the shares may be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the shares may not be sold

unless the shares have been registered or qualified for sale in such state or an exemption from regulation or qualification is available and is complied with. Sales of shares must also be made by us in compliance with all other applicable state securities laws and regulations.

We shall pay all expenses of the registration of the shares.

INTERESTS OF NAMED EXPERTS AND COUNSEL

If and when offered, the validity of the securities being registered hereunder will be passed upon for us by Dickstein Shapiro Morin & Oshinsky LLP. Attorneys of Dickstein Shapiro Morin & Oshinsky LLP beneficially own shares of common stock and warrants to purchase additional shares of our common stock, the aggregate value of which exceeds $50,000.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the Securities and Exchange Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of our Securities and Exchange Commission filings are also available to the public from the Securities and Exchange Commission's Website at "http://www.sec.gov." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to ir@DiscoveryLabs.com or contact John G. Cooper, our Senior Vice President, Chief Financial Officer, at our address as set forth above.

We maintain a Website at "http://www.DiscoveryLabs.com" (this is not a hyperlink, you must visit this website through an Internet browser). Our Website and the information contained therein or connected thereto are not incorporated into this Registration Statement.

We have filed with the Securities and Exchange Commission a registration statement (which contains this prospectus) on Form S-3 under the Securities Act relating to the common stock we are offering by this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us and the common stock. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the Registration Statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

INFORMATION INCORPORATED BY REFERENCE

The Securities and Exchange Commission allows us to "incorporate by reference" the information 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 information that we file later with the Securities and Exchange Commission will automatically update and supersede this information. We incorporate by reference the documents filed with Securities and Exchange Commission listed below:

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as amended by our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2002 filed on April 30, 2003;

2. Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2003, June 30, 2003, and September 30, 2003;
3. Our Current Reports on Form 8-K filed with the Securities and Exchange Commission on February 26, 2003, May 21, 2003, June 5, 2003, June 20, 2003, August 13, 2003, October 22, 2003, and November 25, 2003;
4. The description of our capital stock contained in our Registration Statement on Form 8-A filed with the Securities and Exchange Commission on July 13, 1995.
5. All documents we have filed with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial registration statement and prior to the effectiveness of the registration statement, as well as subsequent to the date of this prospectus and prior to the termination of this offering, shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of the documents.

You may request a copy of these filings, at no cost, by sending an e-mail to ir@DiscoveryLabs.com and requesting any one or more of such filings or by contacting John G. Cooper, our Senior Vice President, Chief Financial Officer, at the following address or telephone number: Discovery Laboratories, Inc., 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901, Attention: John G. Cooper; (215) 340-4699. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

All reports and other documents subsequently filed by us with the Securities and Exchange Commission pursuant to 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 shall be deemed to be incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of such reports and documents. This prospectus also incorporates by reference any documents that we file with the Securities and Exchange Commission after the date of the initial registration statement and prior to the effectiveness of the registration statement. Any statement contained in any document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information contained in this prospectus. We have authorized no one to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document.

EXPERTS

The consolidated financial statements of Discovery Laboratories, Inc. (“Discovery”), appearing in Discovery’s Annual Report (Form 10-K) for the year ended December 31, 2002, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference, which, as to the period from May 18, 1993 (inception) through December 31, 1999, (not presented separately therein) is based on the report of Eisner LLP (formerly Richard A. Eisner & Co. LLP) independent auditors. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

LEGAL MATTERS

Our legal counsel, Dickstein Shapiro Morin & Oshinsky LLP, will render an opinion to the effect that the common stock issued pursuant to this prospectus, if at all, is duly and validly issued, fully paid and non-assessable.

NO DEALER, SALESPERSON OR OTHER PERSON IS AUTHORIZED TO PROVIDE YOU WITH INFORMATION OR TO REPRESENT ANYTHING NOT CONTAINED IN THIS PROSPECTUS. YOU MUST NOT RELY ON ANY UNAUTHORIZED INFORMATION OR REPRESENTATIONS. WE ARE OFFERING TO SELL, AND SEEKING OFFERS TO BUY, ONLY THE SHARES OF DISCOVERY LABORATORIES, INC., COMMON STOCK COVERED BY THIS PROSPECTUS, AND ONLY UNDER CIRCUMSTANCES AND IN JURISDICTIONS WHERE IT IS LAWFUL TO DO SO. THE INFORMATION CONTAINED IN THIS PROSPECTUS IS CURRENT ONLY AS OF ITS DATE, REGARDLESS OF THE TIME OF DELIVERY OF THIS PROSPECTUS OR OF ANY SALE OF THE SHARES.

6,500,000 Shares

DISCOVERY LABORATORIES, INC.

COMMON STOCK

December , 2003

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus supplement. You must not rely on any unauthorized information or representations. This prospectus supplement is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus supplement is current only as of its date.

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PROSPECTUS SUPPLEMENT

PROSPECTUS

DISCOVERY LABORATORIES, INC.

2,200,000 Shares of Common Stock

PROSPECTUS SUPPLEMENT

March 29, 2004

Bear, Stearns & Co. Inc.