

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

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

**DISCOVERY LABORATORIES, INC.**

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

94-3171943

(I.R.S. Employer Identification Number)

2600 Kelly Road, Suite 100  
Warrington, Pennsylvania 18976-3622

(Address, Including Zip Code and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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**Approximate date of commencement of proposed sale to public:** From time to time or at one time after this registration statement becomes effective in light of market conditions and other factors.

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

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

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

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

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

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(1)(2)
Common stock, par value \$.001 per share	8,444,445	\$2.17	\$18,324,446	\$1,960.72

(1) Also registered hereby are such additional and indeterminable number of shares as may be issuable due to adjustments for changes resulting from stock dividends, stock splits and similar changes.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) promulgated under the Securities Act of 1933, as amended, by taking the average of the high and low sales price of the common stock on The Nasdaq Global Market on November 30, 2006. Pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended, we are also registering additional shares of common stock which may become issuable pursuant to the anti-dilution provisions set forth in the Warrant Agreement, dated October 25, 2006, by and between Discovery Laboratories, Inc. and PharmaBio Development Inc. d/b/a NovaQuest for the purchase of up to 1,500,000 shares of common stock and the Warrant to Purchase Common Stock, dated November 22, 2006, by and between Discovery Laboratories, Inc. and Capital Ventures International for the purchase of up to 2,314,815 shares of common stock.

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

[SIDE LEGEND] 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, DATED DECEMBER 7, 2006

PROSPECTUS

8,444,445 Shares



Common Stock

This prospectus relates to the resale of up to 8,444,445 shares of our common stock, par value \$.001 per share, which may be sold by the selling stockholders listed on page 19 for their own account. These shares include 3,814,815 shares that are issuable upon the exercise of the warrants issued to the selling stockholders.

The selling stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell their shares of common stock in the section titled "Plan of Distribution" on page 20. We will pay the expenses incurred in registering the shares, including legal and accounting fees.

Our common stock is quoted on The Nasdaq Global Market under the symbol "DSCO." The last reported sale price for our common stock on December 6, 2006 was \$2.33 per share.

**Investing in our common stock involves significant risks. See "Risk Factors" beginning on Page 2.**

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

The date of this prospectus is \_\_\_\_\_, 2006.

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**This prospectus is part of a registration statement we filed with the Securities and Exchange Commission. You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with additional or 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 prospectus.**

## ABOUT THIS PROSPECTUS

You should read this entire prospectus carefully, including the risks of investing discussed under “Risk Factors” beginning on page 2, and the information to which we refer you and the information incorporated into this prospectus by reference, for a complete understanding of our business and this offering. Unless the context requires otherwise, in this prospectus the terms “the Company,” “Discovery,” “we,” “us” and “our” refer to Discovery Laboratories, Inc., a Delaware corporation, and its consolidated subsidiaries. References to “selling stockholders” refers to the stockholders listed herein under the heading “Selling Stockholders” beginning on page 19, who may sell shares from time to time as described in this prospectus.

## ABOUT DISCOVERY

We are a biotechnology company developing our proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Our technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. We believe that through this technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the neonatal intensive care unit (NICU), critical care unit and other hospital settings, to treat conditions for which there are few or no approved therapies available.

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. Our lead product is Surfaxin<sup>®</sup> (lucinactant). We have filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and have received two Approvable Letters in connection with this NDA.

In addition, we recently announced preliminary results from a Phase 2 clinical trial investigating the use of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants, a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. We are also developing Aerosurf<sup>™</sup>, a proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP), for the treatment of infants at risk for respiratory failure. We are planning to initiate Phase 2 clinical studies with Aerosurf, potentially obviating the need for endotracheal intubation and conventional mechanical ventilation.

As part of our ongoing efforts to address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, we are developing our SRT to potentially address Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), cystic fibrosis and other respiratory conditions.

We are implementing a business strategy that includes: (i) undertaking actions intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States, including (A) preparing to attend a meeting with the FDA in December 2006, with respect to which, in September 2006, we submitted an information package to the FDA addressing questions raised in the second Approvable Letter, which focused on the Chemistry, Manufacturing and Controls (CMC) portion of our NDA, (B) preparing our response to the second Approvable Letter, and (C) completing analysis and remediation of recent manufacturing issues; (ii) investing in development of SRT pipeline programs, including Aerosurf, which uses the aerosol-generating technology rights that we have licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc.; (iii) continued investment in our quality systems and our manufacturing capabilities, including our manufacturing facility in Totowa, New Jersey that we acquired in December 2005, to produce surfactant drug products to meet anticipated clinical and commercial requirements of Surfaxin (if approved) as well as pre-clinical, clinical and future commercial needs of our SRT product candidates (if approved) and, potentially, investing in additional facilities to be built or acquired by us in the future; and (iv) seeking investments of additional capital and potentially entering into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates.

## Corporate Information

Surfaxin® and Aerosurf™ are our trademarks. 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 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622. Our telephone number is (215) 488-9300 and our facsimile number is (215) 488-9301. We maintain a website on the Internet at [www.discoverylabs.com](http://www.discoverylabs.com). Information contained in our web site is not a part of this prospectus.

## RISK FACTORS

*An investment in our common stock involves significant risks. You should carefully consider the risks described below or in any applicable prospectus supplement 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 value or 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.*

### **We may not successfully develop and market our products, and even if we do, we may not become profitable.**

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 our 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 before 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, 2006, we have an accumulated deficit of approximately \$240.5 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.

### **Refocusing our business subjects us to risks and uncertainties.**

Since we received our second Approvable Letter from the FDA in April 2006, we have been reassessing the business environment, our position within the biotechnology industry and our relative strengths and weaknesses. As a result of this reassessment, we have implemented significant changes to our operations as part of our overall business strategy. For example, we have reduced the size of our workforce and made changes to senior management. Additional changes to our business will be considered as our management seeks to strengthen financial and operational performance. These changes may be disruptive to our established organizational culture and systems. In addition, consideration and planning of strategic changes diverts management attention and other resources from day to day operations.

### **We may fail to realize the benefits that we expect from our cost-savings initiatives.**

We have undertaken and expect to continue to undertake cost-savings initiatives. However, we cannot assure you that we will realize ongoing cost savings or any other benefits from these initiatives. Even if we realize the benefits of our cost savings initiatives, any cash savings that we achieve may be offset by other costs, such as costs related to ongoing development activities and pre-clinical and clinical studies. Staff reductions may reduce our workforce below the level needed to effectively manage our business and service our development programs. Our failure to realize the anticipated benefits of our cost-savings initiatives could have a material adverse effect on our business, results of operations and financial condition.

**The regulatory approval process for our products is expensive and time-consuming, and the outcome is uncertain. We may not obtain required regulatory approvals for the commercialization of our products.**

To sell Surfaxin or any of our other products under development, we must receive regulatory approvals for each product. The FDA and foreign regulators 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 the safety and effectiveness of each product and the confirmation by the FDA and foreign regulators that, in manufacturing the product, we maintain good laboratory and manufacturing practices during testing and manufacturing. Even if favorable testing data is generated by clinical trials of drug products, the FDA or a foreign regulator, such as the European Medicines Agency (EMA) in the European Union, may not accept or approve a new drug application (NDA, filed with the FDA), a Marketing Authorization Application (MAA, filed with the EMA) or other similar application filed with a foreign regulator. 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.

We have filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued a Form FDA 483 to our then contract manufacturer, Laureate. The FDA cited inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with current good manufacturing practices (cGMPs). The FDA issued an Approvable Letter to us in February 2005 regarding our NDA. To address the Form FDA 483 inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin. In October 2005, the FDA accepted our responses to the Approvable Letter as a complete response, which thereby established April 2006 as the target date for the FDA to complete its review of our NDA. In April 2006, ongoing analysis of data from Surfaxin process validation batches that were manufactured as a requirement for our NDA, indicated that designated stability parameters in periodic stability testing had not been achieved. Therefore, three additional process validation batches will have to be produced. In September 2006, we announced that, although our comprehensive investigation is ongoing, we believe we have identified a most probable root cause of the process validation stability failures. Our investigation continues, however, and we may identify other contributing factors or causes for the process validation stability failure. There can be no assurance that we have identified or will identify the definitive root cause of the process validation stability failure. If we are unable to identify a definitive root cause, we may not be able to manufacture our drug product successfully within our expected timeline, if at all. The investigation is being conducted in compliance with FDA cGMP requirements and covers, among other things, manufacturing processes, test methods, and drug substance suppliers. As part of the investigation, in addition to a variety of audits, tests and experiments, we have manufactured four "investigation batches" of Surfaxin that have passed the critical release specification assays, with stability monitoring ongoing. These investigation batches are not designated as process validation batches but are expected to provide significant data that will support our comprehensive investigation report and a corrective action and preventative action (CAPA) plan. Also in April 2006, the FDA issued a second Approvable Letter to us, requesting certain information primarily focused on the CMC section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. On September 28, 2006, we filed a briefing package and requested a meeting with the FDA. The purpose of this meeting is to clarify the issues identified by the FDA in the second Approvable Letter and reach agreement with the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. The FDA has notified us that a meeting has been scheduled for December 21, 2006. Once we have manufactured new Surfaxin process validation batches and achieved satisfactory stability testing over an acceptable period and have finalized our response to the second Approvable Letter, we will submit to the FDA our formal response to the second Approvable Letter. At that time, the FDA will advise us if it will accept our response to the second Approvable Letter as a complete response and the time frame in which it will complete its review. Even if the FDA accepts our response as a complete response, the FDA might still delay its approval of our NDA or reject our NDA, which would have a material adverse effect on our business.

We filed an MAA with the EMEA for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. At the time of the Surfaxin process validation stability failure, we had responded to the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) and had met with the EMEA to discuss our response. Because our manufacturing issues would not be resolved within the regulatory time frames mandated by the EMEA, we determined in June 2006 to voluntarily withdraw the MAA for Surfaxin for the prevention and rescue treatment of RDS in premature infants. We plan in the future to have further discussions with the EMEA and develop a strategy to potentially gain approval for Surfaxin in Europe.

**If the FDA and foreign regulators do not approve our products, we will not be able to market our products.**

The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. Without regulatory approval, we will not be able to market our products. Further, the FDA or a foreign regulator could withdraw any approvals we obtain, if any, or 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 or a foreign regulator 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.

**Our pending NDA for Surfaxin for the prevention of RDS in premature infants may not be approved by the FDA in a timely manner or at all, which would adversely impact our ability to commercialize this product.**

We submitted an NDA to the FDA for Surfaxin for the prevention of RDS in premature infants. In April 2006, we received a second Approvable Letter from the FDA, which contained a list of inspectional observations on Form 483. Thereafter, we learned that certain process validation batches, which are a part of our NDA, failed to achieve the designated stability parameters in periodic stability testing. These events are expected to significantly delay the review of our NDA. In addition, in responding to the second Approvable Letter and remediating our manufacturing issues, the FDA may request additional information from us, such as data that may be considered necessary to demonstrate that we are able to manufacture Surfaxin with comparable safety and efficacy as the Surfaxin drug product used in our statistically significant pivotal Phase 3 trial. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to obtain FDA approval or further delay associated with the FDA's review process would adversely impact our ability to commercialize our lead product.

**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 has notified us that two of our intended indications for our precision-engineered SRT, BPD in premature infants and ARDS in adults, have been granted designation as Fast Track products under provisions of the Food and Drug Administration Modernization Act of 1997. Designation as a Fast Track product means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The FDA generally will review an NDA for a drug granted Fast Track designation within six months instead of the typical one to three years. Fast Track designation does not accelerate clinical trials nor does it mean that the regulatory requirements are less stringent. Our products may cease to qualify for expedited review and our other drug candidates may fail to qualify for Fast Track designation or expedited review.

**Our ongoing clinical trials may be delayed, or fail, which will harm our business.**

Clinical trials generally take two to five years or more to complete. Like many biotechnology companies, we may suffer significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials or in preliminary findings for such clinical trials. Data obtained from clinical trials 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 and enrollment criteria for the study;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both. Patients may also suffer adverse medical events or side effects that are common to those administered with the surfactant class of drugs such as a decrease in the oxygen level of the blood upon administration.

It is also possible that the FDA or foreign regulators could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If we or any regulator 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 or a foreign regulator on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and foreign regulators on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials.

In addition to our efforts to commercialize Surfaxin for the prevention of RDS in premature infants, we recently announced preliminary results from a Phase 2 clinical trial investigating the use of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants, a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. We are also preparing to conduct multiple Phase 2 pilot studies with Aerosurf for the potential treatment of premature infants in the NICU suffering from neonatal respiratory failure.

**The manufacture of our products is a highly exacting and complex process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.**

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Manufacturing or quality control problems have already and may again occur at our manufacturing facility in Totowa, New Jersey or at a facility of our materials suppliers. Such problems, including, for example, our recent process validation stability failure, require potentially complex, time-consuming and costly investigations to determine the causes and may also require detailed and time-consuming remediation plans, which can further delay the regulatory approval process. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

In December 2005, we acquired the clinical manufacturing facility in Totowa, New Jersey, that was operated by our contract manufacturer at the time, Laureate Pharma, Inc. The facility has been qualified to produce appropriate clinical grade material of our drug product for use in our ongoing clinical studies. With this acquisition, we now maintain a complete manufacturing facility and we will be manufacturing our products. We currently own certain specialized manufacturing equipment, employ certain manufacturing managerial personnel, and we expect to invest in additional manufacturing equipment. However, we may be unable to produce Surfaxin and our other SRT drug candidates to appropriate standards for use in clinical studies or for commercialization. If we do not successfully develop our manufacturing capabilities, it will adversely affect the sales of our products.

In connection with the development of Aerosurf, we expect to rely on third-party contract manufacturers to manufacture the Chrysalis drug device products and components to support our clinical studies and potential commercialization of Aerosurf. Certain of the drug device components must be manufactured in a sterile environment, subject to ongoing monitoring of conformance to product specifications of each device. The manufacturer must be registered with and qualified by the FDA and must conduct its manufacturing activities in compliance with cGMP requirements, or those of foreign regulators. We may be unable to identify a qualified manufacturer to meet our requirements or the manufacturer we identify may be unable to timely comply with FDA, or other foreign regulatory agency, requirements to manufacture the drug product devices or such manufacturer may not manufacture to our specifications for use in clinical studies or, if approved, commercialization. If we do not successfully identify and enter into a contractual agreement with drug device and components manufacturers, it will adversely affect the timeline of our plans for development, the development plan and, if approved, commercialization of Aerosurf.

**If the parties we depend on for supplying our active drug substances and certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.**

We rely on suppliers for our active drug substances and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards for use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. The manufacturing process for the drug product devices used in Aerosurf includes the integration of a number of products, many of which are comprised of a large number of subcomponent parts, that we expect will be produced by one or more manufacturers. We and our suppliers may not be able to (i) produce our drug substances, drug product or drug product devices to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and suppliers, 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.

**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 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.

In December 2004, we restructured our strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of our products in Europe and Latin America. Under the revised alliance, we regained full commercialization rights in key European markets, Central America and South America for SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults. Esteve will focus on Andorra, Greece, Italy, Portugal, and Spain, and now has development and marketing rights to a broader portfolio of potential SRT products. Esteve will pay us a transfer price on sales of Surfaxin and other SRT. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the revised territory. Esteve has agreed to make stipulated cash payments to us upon its achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory. In October 2005, Esteve sublicensed the distribution rights to Surfaxin in Italy to Dompe Farmaceutici S.p.A. (Dompe), a privately owned Italian company. Under the sublicense agreement, Dompe will be responsible for sales, marketing and distribution of Surfaxin in Italy.

If we or Esteve or its sublicensee breach or terminate the agreements that make up such collaboration arrangements or Esteve otherwise fails to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their 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. Accordingly, we may need to enter into additional collaboration agreements and our success may depend upon obtaining additional collaboration partners. In addition, we may depend on our collaborators' expertise and dedication of sufficient resources to develop and commercialize our proposed products.

In December, 2005, we entered into a Strategic Alliance Agreement with Chrysalis to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. Under the agreement, we have exclusive rights to Chrysalis' proprietary aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Chrysalis will assist with the development of certain combination drug-device surfactant products, and provide certain additional consultative services to us in connection with combination drug-device surfactant products, provided that certain terms and conditions are satisfied. Additionally, Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device 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 - We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates."

**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 working capital will be adequate to satisfy our capital needs through the third quarter of 2007, before taking into account any amounts that may be available through the Committed Equity Financing Facility (CEFF) that we entered into with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in April 2006. 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 new capital lease arrangements, if available. 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 recently financed our activities through use of the CEFF with Kingsbridge, the NovaQuest loan, a \$10 million private placement transaction that we recently completed (see discussion at "Recent Financial Transactions") and our capital equipment lease financing arrangement with General Electric Credit Corporation (GECC), which expired on October 31, 2006. Our use of the CEFF is subject to certain conditions, including a limitation on the total number of shares of common stock that we may issue under the CEFF (approximately 8.0 million shares were available for issuance under the CEFF as of November 30, 2006). In addition, Kingsbridge is not obligated to purchase shares from us under the CEFF on any trading day during the draw-down period on which the volume weighted average price of our common stock (VWAP) is less than the greater of (i) \$2.00 or (ii) 85 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period. In addition, Kingsbridge has the right under certain circumstances to terminate the CEFF, including upon the occurrence of a material adverse event.

Our equipment lease financing arrangement with GECC expired on October 31, 2006. We continue to engage in discussions with GECC, which has agreed in the near term to discuss our financing needs on a month to month basis. We are also considering alternative arrangements with other financing entities; however, there is no assurance that our discussions with GECC will continue to be successful or that any alternative arrangements will be successfully concluded. If we are successful in arranging for property and lease financing arrangements, there is no assurance that such arrangements will be on terms that are favorable to us or sufficient to meet our capital financing needs over the term of the arrangement. If we do not obtain additional capital financing, we may not be able to execute on our business plan, in particular our manufacturing strategy, and be forced to delay or scale back our activities.

On June 20, 2006, we announced that we have engaged Jefferies & Company, Inc., the New York-based investment banking firm, to assist us in identifying and evaluating strategic alternatives intended to generate additional funds and enhance the future growth potential of our surfactant replacement therapy pipeline and maximize shareholder value. On November 22, 2006, we sold securities in a private placement to one selected institutional investor for gross proceeds of \$10.0 million. Under the terms of the financing, we sold approximately 4.6 million newly-issued shares of our common stock at a price of \$2.16 per share and issued a warrant with a five-year term exercisable for approximately 2.3 million shares of common stock at an exercise price of \$3.18 per share, subject to adjustment as provided in the warrant. We are also considering multiple strategic alternatives, including, but not limited to, potential business alliances, commercial and development partnerships, additional financings, business combinations and other similar opportunities. No assurances can be given that our evaluation will lead to any additional specific actions or transactions or generate additional capital for us.

If we seek additional financing, such additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to receive additional funding or enter into business alliances or other similar opportunities, 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. See also "Risk Factors: Our Committed Equity Financing Facilities may have a dilutive impact on our stockholders."

Furthermore, if the market price of our common stock declines as a result of the dilutive aspects of such potential financings, we could cease to meet the financial requirements to maintain the listing of our securities on The Nasdaq Global Market.

**Our Committed Equity Financing Facilities may have a dilutive impact on our stockholders.**

The issuance of shares of our common stock under the CEFF and upon exercise of the warrants we issued to Kingsbridge will have a dilutive impact on our other stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. In addition, if we access the CEFF, we will issue shares of our common stock to Kingsbridge at a discount of between 6% and 10% of the daily volume weighted average price of our common stock during a specified period of trading days after we access the CEFF. Issuing shares at a discount will further dilute the interests of other stockholders.

To the extent that Kingsbridge sells shares of our common stock issued under the CEFF to third parties, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Kingsbridge may cause holders of our common stock to sell their shares, or it may encourage short sales of our common stock or other similar transactions. This could contribute to a decline in the stock price of our common stock.

We may not be able to meet the conditions we are required to meet under the CEFF and we may not be able to issue any portion of the shares potentially available for issuance for future financings, subject to the terms and conditions of the CEFF. In addition, we are dependent upon the financial ability of Kingsbridge to fund the CEFF. Any failure by Kingsbridge to perform its obligations under the CEFF could have a material adverse effect upon us.

## **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 these “Risk Factors”.

Our common stock is listed for quotation on The Nasdaq Global Market. During the twelve month period ended November 30, 2006, the price of our common stock has ranged from \$1.16 to \$8.60. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the twelve month period ended November 30, 2006, the average daily trading volume in our common stock was approximately 1,048,000 shares and the average number of transactions per day was approximately 2,500. 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 Nasdaq Global Market. If the common stock were no longer listed on The Nasdaq Global 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.

**Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our stock incentive plans and upon the exercise of outstanding securities exercisable for shares of our common stock, including employee stock options and warrants that we issue from time to time, could result in substantial additional dilution of our stockholders and could cause our stock price to fall.**

We expect that we will require significant additional capital to continue to execute our business plan and advance our research and development efforts. To the extent that we raise additional capital through the issuance of additional equity securities and through the exercise of outstanding warrants, our stockholders may experience substantial dilution. We may sell shares of our common stock in one or more transactions at prices that may be at a discount to the then-current market value of our common stock and on such other terms and conditions as we may determine from time to time. Any such transaction could result in substantial dilution of our existing stockholders. If we sell shares of our common stock in more than one transaction, stockholders who purchase our common stock may be materially diluted by subsequent sales. Such sales could also cause a drop in the market price of our common stock. As of November 30, 2006 we had 69,578,456 shares of common stock issued and outstanding.

We have a universal shelf registration statement on Form S-3 (File No. 333-128929), filed with the SEC on October 11, 2005, for the proposed offering from time to time of up to \$100 million of our debt or equity securities, of which \$80 million is remaining. We have no immediate plans to sell any securities under this registration statement. However, we may issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

As of November 30, 2006, 11,208,897 shares of our common stock are reserved for issuance pursuant to our Amended and Restated 1998 Stock Option Plan (including 9,420,411 shares underlying outstanding stock options), 6,525,018 shares of our common stock are reserved for issuance upon exercise of outstanding warrants, and 362,972 shares of our common stock are reserved for issuance pursuant to our 401(k) Plan. The exercise of stock options and other securities could cause our stockholders to experience substantial dilution. Moreover, 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. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

If, during the term of certain of our warrants, we declare or make any dividend or other distribution of our assets to holders of shares of our common stock, by way of return of capital or otherwise (including any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction), then the exercise price of such warrants may adjust downward and the number of shares of common stock issuable upon exercise of such warrants would increase. As a result, we may be required to issue more shares of common stock than previously anticipated, which could result in further dilution of our existing stockholders.

**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 November 30, 2006, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 24% 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.

**Our technology platform is based solely on our proprietary precision-engineered surfactant technology.**

Our precision-engineered surfactant technology platform is based on the scientific rationale of using SRT 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 technology platform. Any material problems with our technology platform could have a material adverse effect on our business.

**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 and its wholly owned subsidiary, 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 2017 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 develop and 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 agreements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Johnson & Johnson, Ortho Pharmaceutical and Chrysalis. These agreements require us to make payments and satisfy performance obligations to maintain our rights under these licensing agreements. 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.

Finally, 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:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach;
- our trade secrets or proprietary know-how will otherwise become known;
- our competitors will independently develop similar technology; or
- our competitors will independently discover our proprietary information and trade secrets.

**We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates.**

We do not have experience in marketing or selling pharmaceutical products. As a result of our recent manufacturing problems, we discontinued our commercial activities, which are no longer in our near-term plans. To achieve commercial success for Surfaxin, or any other approved product, we will be dependent upon entering into arrangements with others to market and sell our products.

We may be unable to establish satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates. To obtain the expertise necessary to successfully market and sell Surfaxin, or any other product, will require the development of collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract. Accordingly, we may not have sufficient funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

**We may enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates.**

We may rely on third-party distributors to distribute our products or enter into marketing alliances to sell our products. We may not be successful in entering into distribution arrangements and marketing alliances with third parties. Our failure to successfully enter into these arrangements on favorable terms could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Our dependence on distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including:



- we may be required to relinquish important rights to our products or product candidates;
- we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;
- our distributors or collaborators may experience financial difficulties;
- our distributors or collaborators may not devote sufficient time to the marketing and sales of our products thereby exposing us to potential expenses in terminating such distribution agreements; and
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

We may need to enter into additional co-promotion arrangements with third parties where our own sales force is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements may not be favorable to us. In addition, if we enter into co-promotion arrangements or market and sell additional products directly, we may need to further expand our sales force and incur additional costs.

If we fail to enter into arrangements with third parties in a timely manner or if they fail to perform, it could adversely affect sales of our products. We and any of our third-party collaborators must also market our products in compliance with federal, state and local laws relating to the providing of incentives and inducements. Violation of these laws can result in substantial penalties.

We have announced our intention to seek to market and sell Surfaxin through one or more marketing partners, potentially both in the United States and abroad. Although our agreement with Esteve provides for collaborative efforts in directing a global commercialization effort, we have somewhat limited influence over the decisions made by Esteve or their sublicensees or the resources they devote to the marketing and distribution of Surfaxin products in their licensed territory, and Esteve or their sublicensees may not meet their obligations in this regard. Our marketing and distribution arrangement with Esteve may not be successful, and we may not receive any revenues from it. Also, we may not be able to enter into marketing and sales agreements on acceptable terms, if at all, for Surfaxin in territories not covered by the Esteve agreement, or for any of our other product candidates.

**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 our key personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs.

In order to lower our cost structure and re-align our operations with business priorities, in April 2006, we reduced our staff levels and reorganized our corporate structure. The workforce reduction totaled 52 employees, representing approximately 33% of our workforce, and was focused primarily on commercial infrastructure, the development of which is no longer in our near-term plans. Included in the workforce reduction were three senior executives. As a consequence of this reduction in force, our dependence on our remaining management team is increased. If we find it necessary or advisable to hire additional managers, a portion of the expected cost savings from our recent restructuring might not be realized.

To retain and provide incentives to certain of our key continuing executives, we entered into amended and new employment agreements with our executive management and other officers, which agreements provide for employment for a stated term, subject to automatic renewal, severance payments in the event of termination of employment, enhanced severance benefits in the event of a change of control and equity incentives in the form of stock and option grants. Although these employment agreements generally include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the applicable noncompete provisions can be difficult and costly to monitor and enforce. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. 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. 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, four products are specifically approved for the prevention of RDS in premature infants. There are no approved drugs that are specifically indicated for the prevention and treatment of ALI/ARDS in adults and current therapy consists of general supportive care and mechanical ventilation. See Item 1: "Business - Competition" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005.

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 if 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 million per occurrence and \$10 million 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 before 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.

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

Provisions of our Restated Certificate of Incorporation, as amended, our Shareholders Rights Agreement 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 Restated Certificate of Incorporation, as amended, 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. 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, before the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock. We have adopted a Shareholders Rights Agreement which under certain circumstances would significantly impair the ability of third parties to acquire control of us without prior approval of our Board of Directors thereby discouraging unsolicited takeover proposals. The rights issued under the Shareholders Rights Agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors.

**The failure to prevail in litigation or the costs of litigation, including securities class action and patent claims, could harm our financial performance and business operations.**

We are potentially susceptible to litigation. For example, as a public company, we are subject to claims asserting violations of securities laws, as well as derivative actions. In particular, in early May 2006, four shareholder class actions and two derivative actions were filed in the United States District Court for the Eastern District of Pennsylvania against the Company and its Chief Executive Officer, Robert J. Capetola, Ph.D. Certain of the complaints also named other of our officers and certain of our directors. The class actions were consolidated under a Consolidated Amended Complaint, filed on August 9, 2006, and on November 1, 2006, the court dismissed the Consolidated Amended Complaint without prejudice and granted plaintiffs leave to file an amended Consolidated Amended Complaint by November 30, 2006. Plaintiffs filed a Second Consolidated Amended Complaint on November 30, 2006.

Two shareholder derivative complaints were filed in May and June 2006, respectively, in the United States District Court for the Eastern District of Pennsylvania against our Chief Executive Officer, Robert J. Capetola, and our directors. These complaints were initially subject to a stipulation agreement between the parties providing that we were not required to respond to these consolidated complaints until 60 days following defendants' answer or a dispositive ruling on a motion to dismiss filed in response to the consolidated amended complaint in the class actions, described above. However, on November 28, 2006, the court issued an order directing that the plaintiffs shall file a consolidated amended complaint by December 29, 2006 and we shall answer or otherwise respond to the complaint by January 26, 2007.

We intend to vigorously defend these actions. The potential impact of these actions, all of which generally seek unquantified damages, attorneys fees and expenses, is uncertain. Additional actions based upon similar allegations, or otherwise, may be filed in the future. There can be no assurance that an adverse result in these proceedings would not have a potentially material adverse effect on our business, results of operations and financial condition.

We have from time to time been involved in disputes arising in the ordinary course of business, including in connection with the termination of certain commercial programs following the April 2006 process validation stability failures. Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, we believe they are unlikely to have a material adverse effect on our financial condition or results of operations. However, there can be no assurance that we will be successful in any proceeding to which we may be a party.

In addition, as a biotechnology company, our processes and potential products may conflict with patents that have been or may be granted to competitors, academic institutions or others. We cannot ensure that our products or methods do not infringe upon the patents or other intellectual property rights of third parties. As the biotechnology and pharmaceutical industries expand and more patents are filed and issued, the risk increases that our patents or patent applications for our product candidates may give rise to a declaration of interference by the U.S. Patent and Trademark Office, or to administrative proceedings in foreign patent offices, or that our activities lead to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal proceedings against us seeking substantial damages or seeking to enjoin us from conducting research and development activities.

### **FORWARD-LOOKING STATEMENTS**

This prospectus contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. The forward-looking statements include all matters that are not historical facts and include, without limitation: statements concerning our research and development programs and planning for and timing of any clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; plans to seek collaboration arrangements and strategic alliances with pharmaceutical companies or others to develop, manufacture and market products; the research and development of particular compounds and technologies; the period of time for which our existing resources will enable us to fund our operations; and anticipated cost savings and accounting charges arising out of our recent workforce reductions and corporate restructuring.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 risk that financial conditions may change;
- risks relating to the progress of our research and development;
- the risk that we will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies);
- risks that the FDA or other regulatory authorities may not accept any applications we file;
- risks that the FDA or other regulatory authorities will not approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product;
- risks that the FDA or other regulatory authorities may delay consideration of any applications that we file;
- risks relating to the ability of our third party materials, drug substance and device suppliers and development partners to provide us with adequate supplies of materials, drug substance and devices to support manufacture of drug product for initiation and completion of any of our clinical studies;
- risks relating to our drug manufacturing operations;
- risks relating to the integration of our manufacturing operations into our existing operations;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;
- risks relating to our ability and the ability of our collaborators and development partners to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies;
- risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements;
- the risk that we or our marketing partners will not succeed in developing market awareness of our products;
- the risk that we or our marketing partners will not be able to attract or maintain qualified personnel;
- risks relating to the development of competing therapies and/or technologies by other companies;
- risks relating to our recent workforce reductions and corporate restructuring;
- risks relating to the impact of litigation that has been and may be brought against us and our officers and directors; and
- other risks and uncertainties detailed in Part II, Item 1A: Risk Factors and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2005, and those described from time to time in our future reports filed with the Securities and Exchange Commission (SEC).

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval.

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

## **RECENT FINANCIAL TRANSACTIONS**

### **Credit Facility Restructuring**

On October 25, 2006, we and PharmaBio Development Inc. (d/b/a NovaQuest) ("NovaQuest"), the strategic partnering group of Quintiles Transnational Corp., entered into a Second Amended and Restated Loan Agreement (the "Loan Agreement") and a Second Amended and Restated Security Agreement (the "Security Agreement") in order to restructure NovaQuest's existing \$8.5 million loan to us. The maturity date of the loan has been extended by 40 months, from December 31, 2006 to April 30, 2010. Beginning October 1, 2006, interest shall accrue at the prime lending rate of Wachovia Bank, N.A., subject to change when and as such rate changes, compounded annually and shall be payable on the maturity date. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium.

Pursuant to the Loan Agreement, we issued to NovaQuest a Second Amended and Restated Promissory Note (the "Note"), which replaces and supersedes the Note dated as of December 10, 2001, which was amended and restated as of November 3, 2004. Our obligations to NovaQuest under the Note, the Loan Agreement and the Security Agreement are secured by an interest in substantially all of our assets, subject to limited exceptions set forth in the Security Agreement.

On October 25, 2006, in consideration of NovaQuest's agreement to restructure the loan, we and NovaQuest entered into a Warrant Agreement (the "Warrant Agreement"), pursuant to which NovaQuest has the right to purchase 1,500,000 shares of our common stock at an exercise price equal to \$3.5813 per share, subject to adjustment as provided in the warrant. The Warrant Agreement has a seven-year term and is exercisable, in whole or in part, for cash, cancellation of a portion of our indebtedness under the Loan Agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. The warrant was issued to NovaQuest in a private transaction exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended. Under the Warrant Agreement, we agreed to file a registration statement with the SEC with respect to the resale of the shares issuable upon exercise of the warrants. NovaQuest has agreed to reimburse us for up to \$20,000 of expenses incurred by us in connection with the registration.

### **Private Placement**

On November 22, 2006, we entered into a Securities Purchase Agreement and a Registration Rights Agreement with Capital Ventures International, pursuant to which we issued (i) 4,629,630 shares of our common stock at a price per share of \$2.16 for an aggregate purchase price of \$10,000,000, and (ii) a Warrant to purchase up to 2,314,815 shares of our common stock at an exercise price of \$3.18 per share, subject to adjustment as provided in the warrant.

Pursuant to the Registration Rights Agreement, we agreed to file a registration statement with the SEC, of which this prospectus is a part, with respect to the resale of the shares of common stock and shares issuable upon exercise of the Warrant. Under the Securities Purchase Agreement, we agreed that, until the later of 75 days after the closing of the transaction or the effective date of the registration statement, with certain exceptions (including strategic alliances agreements in support of the development of our drug product pipeline), we will not, directly or indirectly, file any registration statement with the SEC other than the registration statement of which this prospectus is a part, or offer, sell, grant any option to purchase, or otherwise dispose of (or announce any of the foregoing) any of its equity or equity equivalent securities (as described in such agreement).

In connection with this financing, we also entered into a related Engagement Letter with Jefferies & Co., Inc. (Jefferies), who acted as exclusive placement agent for the offering. Pursuant to the Engagement Letter, we paid Jefferies a fee of 5% of the gross proceeds resulting from the offering.

The net proceeds of the private placement were approximately \$9,420,000 after deducting the estimated underwriting discount (5%) and the estimated related offering expenses (\$80,000). We currently anticipate using the net proceeds from this offering primarily for:

- Regulatory, clinical and manufacturing activities intended to gain FDA regulatory approval for our lead drug product candidate, Surfaxin for the prevention of RDS in premature infants. Included are activities to support submitting a complete response to the second FDA Approvable Letter (which focused on the CMC section of our new drug application);
- Further development activities of Surfaxin to include novel formulations of Surfaxin and to address additional respiratory diseases and conditions afflicting neonatal and pediatric patients; and
- Development of Aerosurf, our proprietary surfactant replacement therapy in aerosolized form administered through nasal continuous positive airway pressure to potentially obviate the need for endotracheal intubation and conventional mechanical ventilation, for the prevention of RDS in premature infants.

Pending the application of the net proceeds, we are investing the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

### **USE OF PROCEEDS**

We will not receive any proceeds from the sales of common stock by the selling stockholders pursuant to this prospectus.

## SELLING STOCKHOLDERS

The shares of common stock being offered by the selling stockholders are those previously issued to the selling stockholders and those issuable to the selling stockholders upon exercise of their warrants. For additional information regarding the issuances of common stock and the warrants to the selling stockholders, see “Recent Financial Transactions” above. We are registering the shares of common stock in order to permit the selling stockholders to offer the shares for resale from time to time. NovaQuest, a selling stockholder, continues to be the provider of a \$8.5 million credit facility originally established in 2001, amended in 2004 and further amended in October 2006. In addition to the shares issuable under the Warrant Agreement, NovaQuest is a holder of 1,567,695 shares of our common stock and warrants that are exercisable for 893,612 shares of our common stock. Except for the ownership of the shares of common stock and the warrants listed below, the other selling stockholder has not had any material relationship with us within the past three years.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of common stock by the selling stockholders. The second column lists the number of shares of common stock beneficially owned by the selling stockholders, based on their ownership of the shares of common stock and the warrants, as of December 5, 2006, assuming exercise of the warrants held by the selling stockholders on that date, without regard to any limitations on exercise.

The third column lists the shares of common stock being offered by this prospectus by the selling stockholders.

In accordance with the terms of registration rights agreements with the selling stockholders, this prospectus generally covers the resale of that number of shares of common stock equal to the number of shares of common stock issued and the shares of common stock issuable upon exercise of the related warrants, determined as if the outstanding warrants were exercised, as applicable, in full, in each case, as of the trading day immediately preceding the date this registration statement was initially filed with the SEC. The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

Under the terms of the warrant dated November 22, 2006 (discussed below), the warrant shall not be exercisable and Capital Ventures International may not exercise its warrant (i) until a date not less than 61 days following the date that Capital Ventures International provides us with written notice that the warrant shall now be currently exercisable and (ii) to the extent such exercise would cause it, together with its affiliates, to beneficially own a number of shares of common stock which would exceed 9.99% of our then outstanding shares of common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon exercise of the warrants which have not been exercised. The number of shares in the second column does not reflect these limitations. The selling stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Number of Shares of Common Stock Beneficially Owned After Offering
PharmaBio Development Inc., d/b/a NovaQuest <sup>(1)</sup>	3,961,307 <sup>(2)</sup>	1,500,000 <sup>(3)</sup>	2,461,307
Capital Ventures International <sup>(4)</sup>	4,629,630 <sup>(5)</sup>	6,944,445 <sup>(6)</sup>	0

(1) NovaQuest is the strategic partnering group of Quintiles Transnational Corp. and is dedicated to generating alternative growth strategies for pharmaceutical and biotechnology companies to enable them to derive the most value from their product portfolios through innovative strategic partnering solutions.

(2) Consists of 1,567,695 shares of common stock beneficially owned by NovaQuest and warrants beneficially owned by NovaQuest that are exercisable for 2,393,612 shares of common stock.

(3) Consists of 1,500,000 shares of common stock issuable upon exercise of the Warrant Agreement dated October 25, 2006. For the purposes hereof, we assume the issuance of all shares issuable upon exercise of the warrant.

(4) Heights Capital Management, Inc., the authorized agent of Capital Ventures International ("CVI"), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. CVI is affiliated with one or more registered broker-dealers. CVI purchased the shares being registered hereunder in the ordinary course of business and at the time of purchase, had no agreements or understandings, directly or indirectly, with any other person to distribute such shares.

(5) Consists of 4,629,630 shares of common stock purchased pursuant to the Securities Purchase Agreement dated November 22, 2006.

(6) Consists of 4,629,630 shares of common stock purchased pursuant to the Securities Purchase Agreement dated November 22, 2006 and 2,314,815 shares of common stock issuable upon exercise of the warrant dated November 22, 2006. For the purposes hereof, we assume the issuance of all shares issuable upon exercise of the warrant.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. As of November 30, 2006, there were 69,578,456 shares of common stock outstanding.

#### **PLAN OF DISTRIBUTION**

We are registering the shares of common stock previously issued and the shares of common stock issuable upon exercise of the warrants to permit the resale of these shares of common stock by the holders of the common stock and warrants from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. However, we may receive cash consideration from the exercise of the warrants owned by the selling stockholders. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;



- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- sales pursuant to Rule 144;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or reallocated or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock; provided, that NovaQuest has agreed to reimburse us for up to \$20,000 of expenses incurred by us in connection with the registration statement. The total expenses are estimated to be \$65,000, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that the selling stockholders will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights provided in our agreements with the selling stockholders, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the related agreements, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

At any time a particular offer of the shares of common stock is made, a revised prospectus or prospectus supplement, if required, will be distributed. Such prospectus supplement or post-effective amendment will be filed with the SEC to reflect the disclosure of required additional information with respect to the distribution of the shares of common stock. We may suspend the sale of shares by the selling stockholders pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

### **DESCRIPTION OF COMMON STOCK**

This description of our common stock is a summary. You should keep in mind, however, that it is our Certificate of Incorporation and our By-Laws, and not this summary, which defines any rights you may acquire as a stockholder. 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, along with the applicable provisions of Delaware law.

We currently have authorized 180,000,000 shares of common stock, par value \$0.001 per share. As of November 30, 2006, there were 69,578,456 shares of common stock outstanding, which does not include:

- 9,420,411 shares of common stock issuable upon exercise of outstanding stock options, at a weighted average exercise price of \$5.22 per share;
- 6,525,018 shares of common stock issuable upon exercise of outstanding warrants, at a weighted average exercise price of \$5.07 per share;
- an indeterminate number of shares of common stock issuable under our shelf registration statement on Form S-3 (No. 333-128929) filed with the SEC on October 11, 2005;
- 8,022,145 shares of common stock that are available for future issuance in connection with draw-downs under the CEFF, which shares may be resold by Kingsbridge pursuant to our registration statement on Form S-3 (No. 333-133786) filed with the SEC on May 4, 2006;
- 1,788,486 shares of common stock available for future grant under our Amended and Restated 1998 Employee Stock Option Plan; and
- 362,972 shares of common stock available for future issuance under our 401(k) Plan.

## Common 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. Upon 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 The Nasdaq Global Market under the symbol "DSCO".

## Stockholder Rights Plan

The summary description of the Rights set out herein does not purport to be complete, and is qualified in its entirety by reference to the terms and provision of our Shareholder Rights Agreement, dated as of February 6, 2004.

On February 6, 2004, our Board of Directors adopted a Shareholder Rights Agreement. Pursuant to the rights agreement our Board of Directors (i) declared that each stockholder of record as of the close of business on February 6, 2004, would be issued a dividend of one preferred stock purchase right (a "Right") for each share of our common stock held by such stockholder and (ii) determined that each share of common stock issued by us after such date through the Final Expiration Date (as defined below) shall be issued with a tandem Right. Each Right represents the right to purchase one ten-thousandth of a share of our Series A Junior Participating Cumulative Preferred Stock ("Series A Preferred") at an exercise price equal to \$50 per Right (as the same may be adjusted, the "Exercise Price"). The Rights shall be evidenced by certificates for our common stock until the earlier to occur of:

- 10 days following a public announcement that a person or group of affiliated or associated persons (with certain exceptions, an "Acquiring Person") have acquired beneficial ownership of 15% or more of the outstanding shares of our common stock; and
- 10 business days (or such later date as may be determined by action of the Board of Directors before such time as any person or group of affiliated persons becomes an Acquiring Person) following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the outstanding shares of Common Stock (the earlier of such dates being called the "Distribution Date").

The Rights are not exercisable until the Distribution Date. Until a Right is exercised, the holder thereof, as such, will have no rights as a Discovery stockholder, including, without limitation, the right to vote or to receive dividends.

The Rights will expire upon the close of business on February 6, 2014 (the "Final Expiration Date"), unless the Rights are earlier redeemed or exchanged by us, in each case as described below.

The shares of Series A Preferred purchasable upon exercise of the Rights will be entitled, when, as and if declared, to a minimum preferential quarterly dividend payment of 10,000 times the per share amount of dividends declared on our common stock. If no common stock dividend is declared in a quarter, a preferred stock quarterly dividend of \$1.00 per share will be required. Upon our liquidation, holders of Series A Preferred will be entitled to a preferential distribution payment of at least 10,000 times the payment made per share of common stock. Each share of Series A Preferred will entitle the holder to 10,000 votes, voting together with our common stock. Upon any merger, consolidation or other transaction in which shares of our common stock are converted or exchanged, the holders of Series A Preferred will be entitled to receive 10,000 times the amount of consideration received per share of our common stock in respect of such transaction. The Rights are protected by customary anti-dilution provisions.

Because of the nature of the Series A Preferred's dividend and liquidation rights, the fair market value of the one ten-thousandth of a share of Series A Preferred purchasable upon exercise of each Right should approximate the fair market value of one share of our common stock. If any person or group of affiliated or associated persons becomes an Acquiring Person, each holder of a Right, (other than Rights beneficially owned by the Acquiring Person, which become void), will have the right to receive upon exercise and payment of the then current Exercise Price, that number of shares of our common stock having a market value of two times the Exercise Price.

If, after a person or group has become an Acquiring Person, we are acquired in a merger or other business combination transaction, or 50% or more of our consolidated assets or earning power are sold, proper provision will be made so that each holder of a Right (other than Rights beneficially owned by an Acquiring Person, which become void) will thereafter have the right to receive, upon exercise at the then current Exercise Price, that number of shares of common stock of the person with whom we engaged in the foregoing transaction (or its parent), which at the time of such transaction will have a market value of two times the Exercise Price. In lieu of exercise, our Board of Directors may exchange the Rights (other than Rights owned by an Acquiring Person, which become void), in whole or in part, for such securities or other property or rights as the Board may determine, including any class or series of our common stock or preferred stock.

At any time before the time an Acquiring Person becomes such, our Board of Directors may redeem the Rights in whole, but not in part, at a price of \$.001 per Right, subject to adjustment.

We may amend the Rights to the extent and on the conditions set out in the Rights Agreement.

### **Anti-Takeover Provisions**

As a corporation organized under the laws of the State of Delaware, we are subject to Section 203 of the General Corporation Law of the State of Delaware, 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:

- before 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**

Our By-Laws provide that our 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. Our By-laws 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 Directors' 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.

## **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2005, and management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and management's assessment are incorporated by reference in reliance on Ernst & Young LLP's reports, given on their authority as experts in accounting and auditing.

## **LEGAL MATTERS**

If and when offered, the validity of the securities being registered hereunder will be passed upon for us by Dickstein Shapiro LLP.

## **INTERESTS OF NAMED EXPERTS AND COUNSEL**

Attorneys of Dickstein Shapiro LLP beneficially own shares of our common stock, the aggregate value of which exceeds \$50,000.

## **WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and periodic reports, proxy statements and other information with the SEC. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of our SEC filings are also available to the public from the SEC'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](mailto: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>". Our Website and the information contained therein or connected thereto are not incorporated into this registration statement.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act relating to the securities 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 our securities. 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 SEC 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 SEC will automatically update and supersede this information. We incorporate by reference the documents filed with SEC listed below:

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2005, filed with the SEC on March 16, 2006;
2. Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2006, June 30, 2006, and September 30, 2006;
3. Our Current Reports on Form 8-K filed with the SEC on October 11, 2006, October 12, 2006, October 26, 2006, November 9, 2006, and November 22, 2006;
4. The description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on July 13, 1995; and
5. All documents we have filed with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this registration statement and before the effectiveness of the registration statement, as well as after the date of this prospectus and before 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](mailto:ir@DiscoveryLabs.com) and requesting any one or more of such filings or by contacting John G. Cooper, our Executive Vice President, Chief Financial Officer, at the following address or telephone number: Discovery Laboratories, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622, Attention: John G. Cooper; (215) 488-9300. 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 SEC 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 before 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 SEC after the date the registration statement is filed and before 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.

## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 14. Other Expenses of Issuance and Distribution

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of the securities being registered. All of such fees expenses, except for the registration fee, are estimates:

	Amount
Securities and Exchange Commission registration fee	\$ 1,961
Accounting fees and expenses	\$ 10,000
Legal fees and expenses*	\$ 65,000
Transfer agent fees and expenses	\$ 2,000
Printing expenses	\$ 0
Miscellaneous fees and expenses	\$ 0
Total	\$ 78,961

\* NovaQuest has agreed to reimburse us for up to \$20,000 of expenses incurred by us in connection with the registration statement.

#### Item 15. Indemnification of Directors and Officers

Article Eighth of our Certificate of Incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for (i) any breach of their duty of loyalty to the corporation or its stockholders, (ii) acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the General Corporation Law of the State of Delaware or (iv) any transaction from which the director derives an improper personal benefit.

Our By-Laws provide that we shall indemnify our directors and officers, the directors and officers of any of our subsidiaries and any other individuals acting as directors or officers of any other corporation at our request, to the fullest extent permitted by law.

We have entered into indemnification agreements with certain of our executive officers containing provisions that may require us, among other things, to indemnify them against liabilities that may arise by reason of their status or service as officers other than liabilities arising from willful misconduct of a culpable nature and to advance certain expenses incurred as a result of any proceeding against them as to which they could be indemnified. We have obtained limited directors' and officers' liability insurance.

These provisions in our Certificate of Incorporation and our By-Laws do not eliminate the officers' and directors' fiduciary duty, and in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under Delaware law. In addition, each officer and director will continue to be subject to liability for breach of their duty of loyalty to us for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for actions leading to improper personal benefit to the officer or director and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provisions also do not affect an officer's or director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

**Item 16. Exhibits**

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
4.1	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004.	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6, 2004.
4.2	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 6, 2004.
4.3	Form of Class A Investor Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 20, 2003.
4.4	Class B Investor Warrant, dated July 7, 2004, issued to Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on July 9, 2004.
4.5	Warrant Agreement, dated as of November 3, 2004, by and between Discovery and QFinance, Inc.	Incorporated by reference to Exhibit 4.1 of Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.
4.6	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.7	Registration Rights Agreement, dated as of July 7, 2004, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2004.
4.8	Registration Rights Agreement, dated April 17, 2006, by and between Discovery and Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.9	Second Amended and Restated Promissory Note, dated as of October 25, 2006, issued to PharmaBio Development Inc. d/b/a NovaQuest	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.10	Warrant Agreement, dated as of October 25, 2006, by and between Discovery and PharmaBio Development Inc. d/b/a NovaQuest	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.11	Warrant dated November 22, 2006, issued to Capital Ventures International.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
4.12	Registration Rights Agreement, dated as of November 22, 2006, by and between Discovery and Capital Ventures International.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
5.1	Opinion of Dickstein Shapiro LLP, legal counsel.	Filed herewith.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.	Filed herewith.
23.2	Consent of Dickstein Shapiro LLP, legal counsel (included in its opinion filed as Exhibit 5.1 to this registration statement).	Filed herewith.
24.1	Powers of Attorney (included in signature page to this registration statement).	Filed herewith.



## Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*provided, however*, that paragraphs (1)(i) and (1)(ii) do not apply if the registration statement is on Form S-3, Form S-8, or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. If a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## SIGNATURES

Pursuant to the requirement of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Warrington, Commonwealth of Pennsylvania, on the 7th day of December, 2006.

### DISCOVERY LABORATORIES, INC.

By: /s/ Robert J. Capetola  
Robert J. Capetola, Ph.D.  
President and Chief Executive Officer

We, the undersigned officers and directors of Discovery Laboratories, Inc., and each of us, do hereby constitute and appoint each of Robert J. Capetola, Ph.D., and David L. Lopez, CPA, Esq., or any of them, each acting alone, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, to do any and all acts and things in our name, place and stead, in any and all capacities, in connection with this registration statement on Form S-3 under the Securities Act of 1933, as amended, or any registration statement for the same offering that is to be effective upon filing under the Securities Act of 1933, as amended, including, without limitation, to sign for us or any of us in our names in the capacities indicated below any and all amendments or supplements to this registration statement, including any and all stickers and post-effective amendments to the registration statement, and to sign any and all additional registration statements relating to the same offering of securities as this registration statement that are filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission and any applicable securities exchange or securities self-regulatory body, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated on the dates indicated.

<u>Signature</u>	<u>Name &amp; Title</u>	<u>Date</u>
<u>/s/ Robert J. Capetola</u>	Robert J. Capetola, Ph.D. President, Chief Executive Officer and Director	December 7, 2006
<u>/s/ John G. Cooper</u>	John G. Cooper Executive Vice President and Chief Financial Officer	December 7, 2006
<u>/s/Kathleen A. McGowan</u>	Kathleen A. McGowan Controller (Principal Accounting Officer)	December 7, 2006
<u>/s/ Herbert McDade</u>	Herbert McDade, Jr. Chairman of the Board of Directors	December 7, 2006
<u>/s/ W. Thomas Amick</u>	W. Thomas Amick Director	December 7, 2006
<u>/s/ Antonio Esteve</u>	Antonio Esteve, Ph.D. Director Max Link, Ph.D. Director	December 7, 2006
<u>/s/ Marvin E. Rosenthale</u>	Marvin E. Rosenthale, Ph.D. Director	December 7, 2006

## INDEX TO EXHIBITS

The following exhibits are included with this Form S-3.

Exhibit No.	Description	Method of Filing
4.1	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004.	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6, 2004.
4.2	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 6, 2004.
4.5	Form of Class A Investor Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 20, 2003.
4.6	Class B Investor Warrant, dated July 7, 2004, issued to Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on July 9, 2004.
4.7	Warrant Agreement, dated as of November 3, 2004, by and between Discovery and QFinance, Inc.	Incorporated by reference to Exhibit 4.1 of Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.
4.8	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.9	Registration Rights Agreement, dated as of July 7, 2004, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2004.
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4.11	Second Amended and Restated Promissory Note, dated as of October 25, 2006, issued to PharmaBio Development Inc. d/b/a NovaQuest	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.12	Warrant Agreement, dated as of October 25, 2006, by and between Discovery and PharmaBio Development Inc. d/b/a NovaQuest	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.13	Warrant dated November 22, 2006, issued to Capital Ventures International.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
4.14	Registration Rights Agreement, dated as of November 22, 2006, by and between Discovery and Capital Ventures International.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
5.1	Opinion of Dickstein Shapiro LLP, legal counsel.	Filed herewith.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.	Filed herewith.
23.2	Consent of Dickstein Shapiro LLP, legal counsel (included in its opinion filed as Exhibit 5.1 to this registration statement).	Filed herewith.
24.1	Powers of Attorney (included in signature page to this registration statement).	Filed herewith.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
4.14	Registration Rights Agreement, dated as of November 22, 2006, by and between Discovery and Capital Ventures International.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
5.1	Opinion of Dickstein Shapiro LLP, legal counsel.	Filed herewith.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.	Filed herewith.
23.2	Consent of Dickstein Shapiro LLP, legal counsel (included in its opinion filed as Exhibit 5.1 to this registration statement).	Filed herewith.
24.1	Powers of Attorney (included in signature page to this registration statement).	Filed herewith.



December 7, 2006

Board of Directors  
Discovery Laboratories, Inc.  
350 South Main Street, Suite 307  
Doylestown, PA 18901

Discovery Laboratories, Inc.--  
Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel for Discovery Laboratories, Inc., a Delaware corporation (the "Company"), in connection with the preparation of the registration statement on Form S-3 (the "Registration Statement"), as filed with the United States Securities and Exchange Commission (the "SEC") under the Securities Act of 1933, as amended (the "Securities Act"), on December 7, 2006, covering the offering for resale of up to 8,444,445 shares of the Company's common stock, par value \$0.001 per share (the "Common Stock"), which includes (i) 4,629,630 shares (the "Shares") of Common Stock issued to Capital Ventures International ("CVI") pursuant to a Securities Purchase Agreement dated as of November 22, 2006 (the "Purchase Agreement") by and between the Company and CVI, (ii) up to 2,314,815 shares of Common Stock (the "CVI Warrant Shares") which are issuable upon the exercise of the Warrant to Purchase Common Stock, dated November 22, 2006, issued by the Company to CVI (the "CVI Warrant"), and (iii) up to 1,500,000 shares of Common Stock (the "PharmaBio Warrant Shares") which are issuable upon the exercise of the Warrant Agreement, dated October 25, 2006, issued by the Company to PharmaBio Development Inc. (the "PharmaBio Warrant"). The Shares, the CVI Warrant Shares and the PharmaBio Warrant Shares are to be offered for resale on a delayed or continuous basis pursuant to Rule 415 promulgated under the Securities Act by the selling stockholders named in the Registration Statement.

In connection with this opinion, we have examined originals or copies, certified or otherwise identified to our satisfaction, of (i) the Company's Restated Certificate of Incorporation, as amended; (ii) the Company's Amended and Restated By-Laws; and (iii) resolutions adopted by the Company's Board of Directors. We have also examined originals or copies, certified or otherwise identified to our satisfaction, of such records of the Company and such agreements, certificates of public officials, certificates of officers or other representatives of the Company, and such other documents, certificates and records as we have deemed necessary or appropriate as a basis for the opinions set forth herein. As to various questions of fact material to this opinion, we have also relied upon representations and warranties of the Company and upon such certificates and other instruments of officers of the Company and public officials furnished to us by the Company, in each case without independent investigation or verification of their accuracy.

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In our examination, we have assumed (i) the genuineness of all signatures; (ii) the authenticity of all documents submitted to us as originals; (iii) the conformity to original documents of all documents submitted to us as certified, conformed or photostatic, electronic or facsimile copies and the authenticity of the originals of such documents; (iv) the authority of all persons signing any document; (v) the enforceability of all the documents and agreements we have reviewed in accordance with their respective terms against the parties thereto; and (vi) the truth and accuracy of all matters of fact set forth in all certificates and other instruments furnished to us.

Based on and subject to the assumptions, qualifications and limitations set forth herein, we are of the opinion that:

1. The Shares have been duly authorized by all necessary corporate action of the Company and are validly issued, fully paid and nonassessable.
2. The CVI Warrant Shares have been duly authorized for issuance pursuant to the CVI Warrant, and when issued and delivered in the manner described in the CVI Warrant against full payment of the consideration set forth therein, will be validly issued, fully paid and nonassessable.
3. The PharmaBio Warrant Shares have been duly authorized for issuance pursuant to the PharmaBio Warrant, and when issued and delivered in the manner described in the PharmaBio Warrant against full payment of the consideration set forth therein, will be validly issued, fully paid and nonassessable.

No opinion is expressed herein with respect to any laws other than the General Corporation Law of the State of Delaware. No opinion is expressed as to the effect that the law of any other jurisdiction may have upon the subject matter of the opinion expressed herein under conflicts of law principles, rules and regulations or otherwise.

This opinion is expressed as of the date hereof. We assume no obligation to supplement this letter if any applicable laws change as of the date hereof or if we become aware of any new facts that might effect any view expressed herein after the date hereof.

We hereby consent to the filing of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to our Firm under the heading "Legal Matters" in the prospectus forming a part of the Registration Statement. In giving this consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act or the rules and regulations promulgated thereunder by the SEC.

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The foregoing opinion is delivered to the Board of Directors of the Company in connection with the Registration Statement and not for any other purpose.

We wish to call your attention to the fact that the fair market value of all securities of the Company that are beneficially owned by attorneys of this Firm exceeds \$50,000.

Very truly yours,

/s/ Dickstein Shapiro LLP

## Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3 No. 333-xxxxx) and related Prospectus of Discovery Laboratories, Inc. for the registration of 8,444,445 shares of its common stock and to the incorporation by reference therein of our reports dated January 27, 2006, with respect to the consolidated financial statements of Discovery Laboratories, Inc., Discovery Laboratories, Inc. management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting of Discovery Laboratories, Inc., included in its Annual Report (Form 10-K) for the year ended December 31, 2005, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
December 5, 2006