PROSPECTUS SUPPLEMENT NO. 1
(TO PROSPECTUS DATED JUNE 18, 2008)

Filed pursuant to Rule 424(b)(3)
under the Securities Act of 1933 in connection with
Registration Statement No. 333-151536

Common Stock

This Prospectus Supplement No. 1 supplements and amends the prospectus dated June 18, 2008 relating to the resale of up to 20,153,000 shares of our common stock by Kingsbridge Capital Limited ("Kingsbridge").

This prospectus supplement should be read in conjunction with the prospectus dated June 18, 2008 which is to be delivered with this prospectus supplement. This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, including any supplements or amendments to it. All references in the prospectus to "this prospectus" are hereby amended to read "this prospectus (as supplemented and amended)."

We are filing this prospectus supplement to reflect a draw down by us pursuant to the Common Stock Purchase Agreement, dated May 22, 2008, between Kingsbridge and ourselves.

The table appearing under the caption "Selling Stockholder" on page 24 of the prospectus is hereby further supplemented and amended by adding the following to the end of footnote (2) to that table, as previously supplemented and amended:

- "On June 29, 2008, we delivered a notice to Kingsbridge to effect a draw down of up to $2,500,000. The first trading day of the eight day pricing period for this draw down was June 30, 2008. In connection with this draw down, we issued an aggregate of 1,104,850 shares of our common stock to Kingsbridge at an aggregate purchase price of $1,562,500. The settlement dates for this drawdown were July 7, 2008 and July 11, 2008."

Investing in our common stock involves significant risks. See "Risk Factors" beginning on Page 7 of the prospectus, as well as the section entitled "Risk Factors" included in our recent quarterly and annual reports filed with the Securities and Exchange Commission.

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 supplement is July 11, 2008.

PROSPECTUS

20,153,000 Shares

Common Stock

This prospectus relates to the resale of up to 20,153,000 shares of our common stock that we may issue to Kingsbridge Capital Limited ("Kingsbridge") pursuant to a Common Stock Purchase Agreement, dated May 22, 2008, between Kingsbridge and ourselves and a Warrant we issued to Kingsbridge on that date. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder 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 stockholder may sell its shares of common stock in the section titled "Plan of Distribution" on page 25. We will not be paying any underwriting discounts or commissions in this offering. 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 June 3, 2008 was $1.82 per share.

Investing in our common stock involves significant risks. See "Risk Factors" beginning on Page 5.

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 June 18, 2008.

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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

The following summary highlights information contained in this prospectus or incorporated by reference. While we have included what we believe to be the most important information about us and this offering, the following summary may not contain all the information that may be important to you. For a complete understanding of our business and this offering, you should read this entire prospectus carefully, including the risks of investing discussed under "Risk Factors" beginning on page 5, and the information to which we refer you and the information incorporated into this prospectus by reference. Unless the context requires otherwise, in this prospectus the terms "Discovery," "we," "us" and "our" refer to Discovery Laboratories, Inc., a Delaware corporation, and its consolidated subsidiary. References to "selling stockholder" refers to the stockholder listed herein under the heading "Selling Stockholder" on page 24, who may sell shares from time to time as described in this prospectus.

ABOUT DISCOVERY

Discovery Laboratories, Inc. (referred to as "we", "us" and "our") is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory disorders and diseases. Our proprietary technology produces a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. We believe that our proprietary technology makes it possible, for the first time, to develop a series of SRT respiratory therapies to treat conditions for which there are few or no approved therapies available for patients in the Neonatal Intensive Care Unit (NICU), Pediatric Intensive Care Unit (PICU), Intensive Care Unit (ICU) and other hospital settings.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. We have filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA recently issued to us an Approvable Letter, which does not require additional clinical trials. We are also developing Surfaxin for other neonatal and pediatric respiratory conditions, including Bronchopulmonary Dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS, and Acute Respiratory Failure (ARF). Aerosurf™ is our proprietary SRT in aerosolized form and is being developed initially to treat premature infants in the NICU. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of SRT in respiratory medicine.

We also believe that our SRT will potentially address a variety of debilitating respiratory conditions such as Acute Lung Injury (ALI), cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), and asthma, that affect other pediatric, young adult and adult patients in the ICU and other hospital settings.

We have implemented a long-term business strategy that includes: (i) ongoing investment in the development of our SRT pipeline programs, with a primary focus on efforts intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States, life cycle development of Surfaxin for other respiratory conditions prevalent in the NICU and PICU, and developing Aerosurf for neonatal and pediatric conditions; (ii) preparing for the potential commercial launch of Surfaxin in the United States; (iii) seeking collaboration agreements and strategic partnerships in the international and domestic markets for the development and potential commercialization of our SRT pipeline; (iv) continued investment in our quality systems and manufacturing capabilities to meet the anticipated pre-clinical, clinical and potential future commercial requirements of Surfaxin, Aerosurf and our other SRT products; and (v) seeking investments of additional capital, including potentially from business alliances, commercial and development partnerships, equity financings and other similar opportunities, although there can be no assurance that we will identify or enter into any specific actions or transactions.

EQUITY FINANCING WITH KINGSBRIDGE CAPITAL

On May 22, 2008, we entered into a Committed Equity Financing Facility (the "CEFF") with Kingsbridge by way of a Common Stock Purchase Agreement. The Common Stock Purchase Agreement entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration up to an aggregate of the lesser of up to $60 million or up to 19,328,000 shares of our common stock, subject to certain conditions and restrictions. In connection with the CEFF, we entered into a Registration Rights Agreement with Kingsbridge. We also issued a Warrant to Kingsbridge to purchase 825,000 shares of our common stock at a price of $2.506 per share, which is fully exercisable beginning November 22, 2008 and for a period of five years thereafter.

The shares of common stock that may be issued to Kingsbridge under the Common Stock Purchase Agreement and upon exercise of the Warrant will be issued pursuant to an exemption from registration under the Securities Act of 1933, as amended (the "Securities Act"). Pursuant to the Registration Rights Agreement, we have filed a registration statement of which this prospectus is a part, covering the possible resale by Kingsbridge of any shares that we may issue to Kingsbridge under the Common Stock Purchase Agreement or upon exercise of the Warrant. Through this prospectus, Kingsbridge may offer to the public for resale the shares of our common stock that we may issue to it pursuant to the Common Stock Purchase Agreement, or that Kingsbridge may acquire upon exercise of the Warrant.

For a period of 36 months from the first trading day following the effectiveness of this prospectus, we may, from time to time, at our discretion, and subject to certain conditions that we must satisfy, draw down funds under the CEFF by selling shares of our common stock to Kingsbridge. The purchase price of these shares will be at a discount ranging from 6 to 12 percent of the volume weighted average of the price of our common stock for each of the eight trading days following our election to sell shares, or "draw down" under the CEFF. The discount on each of these eight trading days will be determined as follows:

VWAP*	% of VWAP	(Applicable Discount)
Greater than $7.25 per share	94%	6%
Less than or equal to $7.25 but greater than $3.85 per share	92%	8%
Less than or equal to $3.85 but greater than or equal to $1.75 per share	90%	10%
Less than or equal to $1.75 but greater than or equal to $1.15 per share	88%	12%

* As set forth in the Common Stock Purchase Agreement, "VWAP" means the volume weighted average price (the aggregate sales price of all trades of our common stock during each trading day divided by the total number of shares of common stock traded during that trading day) of our common stock during any trading day as reported by Bloomberg, L.P. using the AQR function. The VWAP and corresponding discount will be determined for each of the eight trading days during a draw down pricing period.

During the eight trading day pricing period for a draw down, if the VWAP for any one trading day is less than the greater of (i) $1.15 or (ii) 90 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period, the VWAP from that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount we had initially specified. In addition, if trading in our common stock is suspended for any reason for more than three consecutive or non-consecutive hours during any trading day during a draw down pricing period, that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one eighth of the draw down amount we had initially specified.

We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of stock under the CEFF provide an appropriate means of raising capital.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. Each draw down is limited to the lesser of 3.0 percent of the aggregate closing price market value of our outstanding shares of common stock at the time of the draw down or $10 million. Unless Kingsbridge agrees otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next draw down pricing period. Kingsbridge is not obligated to purchase shares at prices below $1.15 per share.

During the term of the CEFF, without the written consent of Kingsbridge, we may not enter into any equity line or other financing that is substantially similar to the CEFF or agree to issue any shares of common stock or securities of any type that are, or may become, convertible or exchangeable into shares of common stock where the purchase, conversion or exchange price for such common stock is determined using any floating discount or other post-issuance adjustable discount to the market price of common stock. Any future issuance by us of a convertible security that contains provisions that adjust the conversion price of such convertible security solely for stock splits, dividends, distributions or similar events is permitted so long as such convertible security does not contain a provision that adjusts the conversion price as a result of any decline in the market price of the common stock after the issue date of the convertible security, other than a decline resulting directly from stock splits, dividends, distributions or similar events.

The issuance of our common stock under the CEFF or upon exercise of the Warrant will have no effect on the rights or privileges of existing holders of common stock except that the economic and voting interests of each stockholder will be diluted as a result of the issuance. Although the number of shares of common stock that stockholders presently own will not decrease, these shares will represent a smaller percentage of our total shares that will be outstanding after any issuances of shares of common stock to Kingsbridge. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Such issuances will have a dilutive effect and may further decrease our stock price.

Kingsbridge agreed in the Common Stock Purchase Agreement that during the term of the CEFF, neither Kingsbridge nor any of its affiliates, nor any entity managed or controlled by it, will, or will cause or assist any person to, enter into any short sale of any of our securities, as “short sale” is defined in Regulation SHO promulgated under the Securities Exchange Act of 1934, as amended.

Before Kingsbridge is obligated to buy any shares of our common stock pursuant to a draw down, the following conditions, none of which is in Kingsbridge’s control, must be met:

- Each of our representations and warranties in the Common Stock Purchase Agreement must be true and correct in all material respects as of the date when made and as of the date of the applicable draw down notice as though made at that time, except for representations and warranties that are expressly made as of a particular date.

- We must have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required to be performed, satisfied or complied with by us under the Common Stock Purchase Agreement, the Registration Rights Agreement and the Warrant.

- We must have complied in all respects with all applicable federal, state and local governmental laws, rules, regulations and ordinances in connection with the execution, delivery and performance of the Common Stock Purchase Agreement and the consummation of the transactions it contemplates except for any failures to so comply that would not reasonably be expected to have a material adverse effect on us.

- The registration statement that includes this prospectus must be effective under the Securities Act.

- We must not have knowledge of any event that could reasonably be expected to have the effect of causing the registration statement applicable to Kingsbridge’s resale of shares of our common stock to be suspended or otherwise ineffective.

- Trading in our common stock shall not have been suspended by the Securities and Exchange Commission (the “SEC”), The Nasdaq Global Market or the National Association of Securities Dealers and trading in securities generally on The Nasdaq Global Market shall not have been suspended or limited.

- No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by the Common Stock Purchase Agreement.

- No action, suit or proceeding before any arbitrator or any governmental authority shall be pending or, to our knowledge, threatened, and, to our knowledge, no inquiry or investigation by any governmental authority shall have been threatened against us or any of our officers, directors or affiliates seeking to enjoin, prevent or change the transactions contemplated by the Common Stock Purchase Agreement, or seeking material damages in connection with such transactions, except for any action, suit or proceeding which could not reasonably be expected to have a material adverse effect.

- We must have sufficient shares of common stock, calculated using the closing trade price of the common stock as of the trading day immediately preceding a draw down, registered under the registration statement to issue and sell such shares in accordance with such draw down.

- The Warrant must have been duly executed, delivered and issued to Kingsbridge, and we shall not be in default in any material respect thereunder.

- Kingsbridge must have received an opinion from our outside legal counsel in the form previously agreed.

There is no guarantee that we will be able to meet the foregoing conditions or any other conditions under the Common Stock Purchase Agreement or that we will be able to draw down any portion of the amounts available under the CEFF.

We also entered into a Registration Rights Agreement with Kingsbridge. Pursuant to the Registration Rights Agreement, we have filed a registration statement, which includes this prospectus, with the SEC relating to Kingsbridge's resale of any shares of common stock purchased by Kingsbridge under the Common Stock Purchase Agreement or issued to Kingsbridge under the Registration Rights Agreement or as a result of the exercise of the Warrant. The effectiveness of this registration statement is a condition precedent to our ability to sell common stock to Kingsbridge under the Common Stock Purchase Agreement. We are entitled in certain circumstances, including the existence of certain kinds of nonpublic information, to deliver a blackout notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement of which this prospectus is a part is not effective in circumstances not permitted by the Registration Rights Agreement, then we must pay amounts to Kingsbridge, or issue Kingsbridge additional shares in lieu of payment, calculated by means of a varying percentage of an amount based on the number of shares held by Kingsbridge that were purchased pursuant to the draw down and the change in the market price of our common stock between the date the blackout notice is delivered (or the registration statement is not effective) and the date the prospectus again becomes available.

Kingsbridge may terminate the CEFF upon one business day's notice to us if we enter into a transaction prohibited by the Common Stock Purchase Agreement without Kingsbridge's prior written consent or if a material adverse effect relating to our business continues for 10 trading days after we receive notice from Kingsbridge of the material adverse effect. Kingsbridge may also terminate the CEFF upon one business day's notice to us at any time if a registration statement is not initially declared effective in accordance with the Registration Rights Agreement. We may terminate the CEFF upon one business day's notice to Kingsbridge, except that we may not terminate the CEFF during any draw down pricing period. In addition, either we or Kingsbridge may terminate the CEFF upon one business day's notice if the other party has breached a material representation, warranty or covenant to the Common Stock Purchase Agreement and such breach is not remedied within 10 trading days after notice of such breach is delivered to the breaching party.

The foregoing summary of the CEFF does not purport to be complete and is qualified by reference to the Common Stock Purchase Agreement, the Registration Rights Agreement and the Warrant, copies of which have been filed or incorporated by reference as exhibits to the registration statement of which this prospectus is a part.

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. 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, and in the documents incorporated therein by reference before deciding to invest in our securities. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. The following risks, among others, could cause our actual results, performance, achievements or industry results to differ materially from those expressed in our forward-looking statements contained herein and presented elsewhere by management from time to time. If any of the following risks actually occurs, our business prospects, financial condition or results of operations could be materially harmed. In such case, the market price of our securities would likely and you could lose all or part of your investment.

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 need to continue to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval activities 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 March 31, 2008, we have an accumulated deficit of approximately $298.0 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.

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 our products under development, including Surfaxin, 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 are generated by clinical trials of drug products, the FDA or a foreign regulator, such as the European Medicines Agency (EMEA), may not accept or approve an NDA or Marketing Authorization Application (MAA) filed by a pharmaceutical or biotechnology company for such drug product. To market our products or conduct clinical trials outside the United States, we also must comply with foreign regulatory requirements governing marketing approval for pharmaceutical products and the conduct of human clinical trials.

We have filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants, which is the subject of a third Approvable Letter. On May 1, 2008, the FDA issued a third Approvable Letter to us. We have requested a meeting with the FDA, which is scheduled to occur on June 18, 2008 by teleconference, to confirm our approach to responding to certain items identified in this Approvable Letter. If our approach is confirmed, we anticipate submitting our response to the Approvable Letter in June 2008. This timeline could be extended based on our discussions with the FDA as well as other factors. If the FDA accepts our formal response to the Approvable Letter as a complete response, we believe that the FDA may classify our response as a Class 1 resubmission, which will result in a 60-day target review period. The FDA might still delay its approval of our NDA or reject our NDA, which would have a material adverse effect on our business. See also "Risk Factors – 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 prevent our commercializing this product in the United States and adversely impact our ability to commercialize this product elsewhere."

We filed an MAA with the EMEA for clearance to market Surfaxin for the prevention of RDS in premature infants in Europe. In April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our then-contract manufacturer as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. As we determined that we could not resolve the related manufacturing issues within the regulatory time frames mandated by the EMEA procedure for consideration of our MAA, in June 2006, we voluntarily withdrew the MAA without fully resolving certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials. We plan in the future to have further discussions with the EMEA and potentially develop a strategy to 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 are not able to market our products. Further, even if we were to succeed in gaining regulatory approvals for any of our products, the FDA or a foreign regulator could at any time withdraw any approvals granted 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, or 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. Any failure to obtain regulatory approval or any withdrawal or significant restriction on our ability to market our products after approval would have a material adverse effect on our business.

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 prevent our commercializing this product in the United States and adversely impact our ability to commercialize this product elsewhere.

In April 2006, the FDA issued a second Approvable Letter to us with respect to our NDA for Surfaxin for the prevention of RDS in premature infants. In October 2007, we filed our complete response to the second Approvable Letter and the FDA established May 1, 2008 as its target to complete review of our NDA. On May 1, 2008, the FDA issued to us a third Approvable Letter. Of the items listed in the Approvable Letter, we believe that the most important involve justifying and finalizing one acceptance criterion for Surfaxin biological activity and limited acceptance criteria for lipid drug substance impurities and that we and the FDA can reach agreement on these acceptance criteria. We have requested a meeting with the FDA, which is scheduled to occur on June 18, 2008 by teleconference, to confirm our approach to respond to these and certain other limited items identified in this Approvable Letter. If this meeting confirms our approach, we anticipate submitting our response to the Approvable Letter in June 2008. However, this timeline could be extended based on our discussions with the FDA as well as other factors. If the FDA accepts our response as a complete response, we believe that the FDA may classify our complete response as a Class 1 resubmission, which will result in a 60-day target review period (as compared to a Class 2 resubmission would result in a 6-month target review period). 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. We believe that other potential products in our SRT pipeline may also qualify for Fast Track designation. 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, 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. 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. Moreover, even if we are successful in gaining Fast Track designation, other factors could result in significant delays in our development activities with respect to our Fast Track products.

Our research and development activities involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes.

Development risk factors include, but are not limited to whether we, or our third party collaborators and providers, will be able to:

- complete our pre-clinical and clinical trials of our SRT product candidates with scientific results that are sufficient to support further development and/or regulatory approval;
- receive the necessary regulatory approvals;
- obtain adequate supplies of surfactant active drug substances, manufactured to our specifications and on commercially reasonable terms;
- perform under agreements to supply the drug substances, medical device components and related services necessary to manufacture our SRT drug product candidates, including Surfaxin and Aerosurf;
- successfully resolve the remaining matters identified by the FDA in the May 1, 2008 Approvable Letter;
- provide for sufficient manufacturing capabilities, at our manufacturing operations in Totowa and with third-party contract manufacturers, to produce sufficient SRT drug product, including Surfaxin, and aerosolization systems to meet our pre-clinical and clinical development requirements;
- successfully develop and implement a manufacturing strategy for our aerosolization systems and related materials to support clinical studies of Aerosurf; and
- obtain capital necessary to fund our research and development efforts, including our supportive operations, manufacturing and clinical trials requirements.

Because these factors, many of which are outside our control, could have a potentially significant effect on our development activities, the success, timing of completion, and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things:

- slow patient enrollment;
- long treatment time required to demonstrate effectiveness;
- lack of sufficient clinical supplies and material;
- adverse medical events or side effects in treated patients;
- lack of compatibility with complementary technologies;
- failure of a product candidate to demonstrate effectiveness; and
- lack of sufficient funds.

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our SRT products. Failure to obtain and maintain regulatory approval and generate revenues from the sale of our products would have a material adverse effect on our financial condition and results of operations and could reduce the market value of our common stock.

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 that 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 many factors, including the rate at which patients are enrolled. Delays in patient enrollment in clinical trials may occur, which would be likely to result in increased costs, program delays, or both.

Patient enrollment 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 willingness of patients or their parents or guardians to participate in the clinical trial;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

If we succeed in achieving our patient enrollment targets, patients that enroll in our clinical trials could suffer adverse medical events or side effects that are known to occur with the administration of the surfactant class of drugs generally, 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 gain approval of Surfaxin for the prevention of RDS in premature infants, we are currently conducting a Phase 2 clinical trial to evaluate the use of Surfaxin in children up to two years of age suffering from Acute Respiratory Failure. We are also planning to initiate clinical studies in support of other products in our SRT pipeline, including planned Phase 2 clinical trials with respect to Aerosurf for the treatment and prevention of RDS in premature infants in the NICU. All of these clinical trials will be time-consuming and potentially costly. Should we fail to complete our clinical development programs or should such programs yield unacceptable results, such failures would have a material adverse effect on our business.

The manufacture of our drug products is a highly exacting and complex process, and if we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or drug substances, this could cause us to delay any potential clinical program or product launch or, following approval, cause us to experience shortages of products inventories.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also periodically inspect these facilities to confirm compliance with current good manufacturing procedures (cGMP) or other similar requirements that the FDA or foreign regulators establish. Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. It must be aseptically manufactured at our facility as a sterile, liquid suspension and requires ongoing monitoring of drug product stability and conformance to specifications.

The manufacture of pharmaceutical products requires significant expertise and compliance with strictly enforced federal, state and foreign regulations. We, our contract manufacturers or our materials and drug substances suppliers may experience manufacturing or quality control problems that could result in a failure to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, which is necessary to continue manufacturing our drug products, materials or drug substances. Other problems that may be encountered include:

- the need to make necessary modifications to qualify and validate a facility;
- difficulties with production and yields, including scale-up requirements and achieving adequate capacity;
- availability of raw materials and supplies;
- quality control and assurance; and
- shortages of qualified personnel.

Such a failure could result in product production and shipment delays or an inability to obtain materials or drug substances supplies.

Manufacturing or quality control problems have already occurred and may again occur at our Totowa, New Jersey facility or may occur at the facilities of a contract manufacturer or our materials or drug substances suppliers. Such problems may require potentially complex, time-consuming and costly comprehensive investigations to determine the root causes of such problems and may also require detailed and time-consuming remediation efforts, which can further delay a return to normal manufacturing and production activities. Any failure by our own manufacturing operations or by the manufacturing operations of any of our suppliers to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our ability to manufacture our drug products, which in turn would adversely affect our clinical research activities and our ability to develop and gain regulatory approval to market our drug products.

Since we acquired our manufacturing operations in Totowa, New Jersey in December 2005, we have been manufacturing our drug products. This is the only facility at which we produce our drug product. Any interruption in manufacturing operations at this location could result in our inability to satisfy our needs for planned clinical trials, and, if approved, commercial requirements for Surfaxin. A number of factors could cause interruptions, including:

- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages or slowdowns;
- damage to or destruction of the facility;
- regional power shortages; and
- product tampering.

To assure adequate drug supplies and continued compliance with cGMP and other FDA or foreign regulatory requirements, we own certain specialized manufacturing equipment, employ experienced manufacturing senior executive and managerial personnel, and continue to invest in enhanced quality systems and manufacturing capabilities. However, we may nevertheless be unable to produce Surfaxin and our other SRT drug candidates to appropriate standards. If we are unable to successfully develop and maintain our manufacturing capabilities and comply with cGMP, it will adversely affect our clinical development activities and, potentially, the sales of our products.

If we fail to maintain relationships with our manufacturers, assemblers and integrator of our aerosolization systems, or if we fail to identify additional, qualified replacement manufacturers, assemblers and integrators to manufacture subcomponents and integrate our initial prototype aerosolization system or our anticipated next-generation and later development versions of our capillary aerosolization technology, the timeline of our plans for the development and, if approved, commercialization of Aerosurf could suffer.

In connection with the development of aerosol formulations of our SRT, including Aerosurf, we currently plan to rely on third-party contract manufacturers to manufacture, assemble and integrate the subcomponents of our capillary aerosolization technology to support our clinical studies and potential commercialization of Aerosurf. Certain of these key components must be manufactured in an environmentally-controlled area and, when assembled, the critical product-contact components and patient interface systems must be packaged and sterilized. Each of the aerosolization system devices must be quality-control tested prior to release and monitored for conformance to designated product specifications, and each manufacturer, assembler and integrator must be registered with the FDA and conduct its manufacturing activities in compliance with cGMP requirements or other FDA or foreign regulatory requirements.

We currently have identified component manufacturers and an integrator to manufacture and integrate our initial prototype aerosolization system that we currently plan to use in early Phase 2 clinical trials. However, we may not be able to identify qualified additional or replacement manufacturers and integrators to manufacture subcomponents and integrate our current prototype or next generation and later development versions of our aerosolization systems or we may not be able to enter into agreements with them on terms and conditions favorable and acceptable to us. In addition, the manufacturers and assemblers and integrators that we identify may be unable to timely comply with FDA, or other foreign regulatory agency, requirements regulating manufactures of combination drug-device products. If we do not successfully identify and enter into a contractual agreements with aerosolization systems and components manufacturers, assemblers and integrators, it will adversely affect the timeline of our plans for the development and, if approved, commercialization of Aerosurf.

If the parties we depend on for supplying our active drug substance 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, materials and excipient products, and third parties for certain manufacturing-related services to produce drug material that meets appropriate content, quality and stability standards for use in clinical trials and, if approved, 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 Aerosurf, a combination drug-device product, includes the integration of a number of components, many of which are comprised of a large number of subcomponent parts that we expect will be produced by potentially a number of manufacturers. We and our suppliers may not be able to (i) produce our drug substances, drug product or drug product devices or related subcomponent parts to appropriate standards for use in clinical studies, (ii) perform to applicable specifications 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.

In some cases, we are dependent upon a single supplier to produce our full requirement of drug substances, drug product or drug product devices. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or vendor and may not be able to 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 our profit margins, if any. Even if we are able to find replacement manufacturers, suppliers and vendors when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. Such delays could have a material adverse effect on our development activities and our business.

If we do not adequately forecast customer demand for our product candidates, including Surfaxin, if approved, our business could suffer.

The timing and amount of customer demand is difficult to predict and the commercial requirements to meet changing customer demand is difficult to predict. If we are successful in gaining regulatory approval of our products, we may not be able to accurately forecast customer demand for our product candidates, including Surfaxin, or respond effectively to unanticipated increases in demand. This could have an adverse effect on our business. If we overestimate customer demand, or attempt to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and timely commercialize our product candidates, we may never require the production capacity that we expect to have available.

Our limited sales and marketing experience may restrict our success in commercializing our product candidates.

We have limited experience in marketing or selling pharmaceutical products and have a limited marketing and sales team. In the second quarter 2006, following receipt of the second Approvable Letter and the occurrence of the process validation stability failures, we discontinued our commercial activities. Therefore, if we are successful in gaining approval to market Surfaxin, we will have to re-establish satisfactory marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates, if approved.

We expect to rely primarily on our marketing and sales team to market Surfaxin, if approved, in the United States. Our pre-approval preparations have included the hiring of experienced management personnel. We have also begun to invest in our medical affairs capabilities to provide for increased scientific and medical educational activities. We do not plan to hire our sales representatives until after we have received approval to market Surfaxin. Developing a marketing and sales team to market and sell products is a difficult, expensive and time-consuming process. Recruiting, training and retaining qualified sales personnel is critical to our success. Competition for skilled personnel can be intense, and we may be unable to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Additionally, we may not be able to provide adequate incentive to our sales force. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, we will have difficulty selling, maintaining and increasing the sales of our products.

We expect to incur significant expenses in developing our marketing and sales team. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, potentially, 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.

The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

Any potential products that we bring to market may not gain or maintain market acceptance by governmental purchasers, group purchasing organizations, physicians, patients, healthcare payers and others in the medical community. If any products that we develop do not achieve an adequate level of acceptance, we may not generate material revenues with these products. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the perceived safety and efficacy of our products;
- the potential advantages over alternative treatments;
- the prevalence and severity of any side effects;
- the relative convenience and ease of administration;
- cost effectiveness;
- the willingness of the target patient population to try new products and of physicians to prescribe our products;
- the effectiveness of our marketing strategy and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

Our strategy with respect to development and marketing of our products, in many cases, is to enter into collaboration agreements and strategic partnerships with third parties. If we fail to enter into these agreements, or if we or the third parties fail to perform under such agreements, it could impair our ability to develop and commercialize our products.

To fund development, clinical testing and marketing and commercialization of our products, our strategy, in many cases, depends upon collaboration arrangements and strategic partnerships with pharmaceutical and other biotechnology companies to develop, market, commercialize and distribute our products. In addition to funding our activities, we may depend on our collaborators' expertise and dedication of sufficient resources to develop and commercialize the covered products. In addition, if our current collaboration arrangements fail to timely meet our objectives, we may need to enter into additional collaboration agreements and our success may depend upon obtaining such additional collaboration partners.

Our collaboration arrangement with Esteve for Surfaxin and certain other of our product candidates is focused on key southern European markets. If we or Esteve should fail to conduct our respective collaboration-related activities in a timely manner, or otherwise breach or terminate the agreements that make up our collaboration arrangements, or if a dispute should arise under our collaboration arrangements, such events could impair our ability to commercialize or develop our products for the Esteve territory in Europe covered by the arrangement. In such events, we may need to seek other partners and collaboration agreements, or we may have to develop our own internal capabilities to market the covered products in the Esteve territory without a collaboration arrangement.

We have recently restructured our strategic alliance with Philip Morris USA, Inc. d/b/a/ Chrysalis (PM USA). Under the restructured arrangement, we are now responsible for finalizing design development for the initial prototype aerosolization device platform and disposable dose packets. Prior to June 30, 2008, PM USA is responsible to make a technology transfer to us of its capillary aerosolization technology to permit us to fully practice our license to this technology in all respects. We expect to rely on our own engineering expertise as well as design engineers, medical device experts and other third party collaborators to advance the development of our capillary aerosolization technology. If PM USA should fail to complete the technology transfer to us, or if we are unable to identify design engineers and medical device experts to support our program in the future, or if we should fail to complete development of the initial prototype aerosolization system as well as next generation versions of the aerosolization system, such events could impair our ability to commercialize or develop our aerosolized SRT products.

We may, in the future, grant to our present or additional collaboration partners rights to license and commercialize our pharmaceutical products. Under such arrangements, our collaboration partners may control key decisions relating to the development and commercialization of the covered products. By granting such rights to our collaboration partners, we would likely limit our flexibility in considering alternative strategies to develop and commercialize our products. If we were to fail to successfully develop these relationships, or if our collaboration partners were to fail to successfully develop, market or commercialize any of the covered products, such failures 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 and our other SRT product candidates. See “Risk Factors – Our limited sales and marketing experience may restrict our success in commercializing our product candidates.”

Under our restructured collaboration arrangement with PM USA, we are responsible for future development of the capillary aerosolization technology, which will require us to build internal development capabilities or enter into future collaboration or other arrangements to gain the engineering expertise required to further develop the technology.

In March 2008, we restructured our collaboration arrangement with PM USA. We now have responsibility for the development of the capillary aerosolization technology and will not have development support from PM USA after June 30, 2008. Our future development of the capillary aerosolization technology is subject to certain risks and uncertainties, including, without limitation:

- We may not be able to complete the development of the initial prototype aerosolization device, if at all, on a timely basis and such inability may delay or prevent initiation of our planned Phase 2 clinical trials;

- We will require sophisticated engineering expertise to continue the development of the capillary aerosolization technology. Although we are building our own internal medical device engineering expertise and have recently begun working with a leading engineering and design firm that has a successful track record of developing innovative devices for major companies in the medical and pharmaceutical industries, there is no assurance that our efforts will be successful or that we will be able to identify other potential collaborators to complete the development of the next-generation aerosolization system and enter into agreements with such collaborators on terms and conditions that are favorable to us, and, if we are unable to identify or retain design engineers and medical device experts to support our development program, this could impair our ability to commercialize or develop it’s aerosolized drug products;

- We currently hold an exclusive license to the capillary aerosolization technology in the United States from PM USA and outside the United States from Philip Morris Products S.A. (PMPSA). PM USA and PMPSA are no longer affiliated entities; as such, there is a risk that, if we were to require the consent of PMPSA and PM Philip Morris Products S.A. (PMPSA)under the License Agreements, they may not agree on the appropriate course and we may be forced to develop the capillary aerosolization technology in the two territories under different circumstances. Such inconsistencies could have an adverse effect on the our ability to develop the capillary aerosolization technology or to successfully commercialize the Licensed Products in one or both of the territories; and

- We have additional rights under the US License Agreement that are not provided under the International License Agreement. Although the International License Agreement provides for the potential expansion of rights with the consent of PMPSA, there can be no assurance that PMPSA would agree to any such expansion and, as a result, we may be unable to develop and commercialize Licensed Products under its expanded rights outside the United States markets.

To market and distribute our products, 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, either internationally or in the United States. We may not be successful in identifying such third parties or finalizing such arrangements on terms and conditions that are favorable to us. 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 also 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 such parties fail to perform, it could adversely affect sales of our products. We and 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 intend to market and sell Surfaxin outside of the United States, if approved, through one or more marketing partners. 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 its sublicensees or the resources that they may devote to the marketing and distribution of Surfaxin products in their licensed territory, and Esteve or its sublicensees may not meet their obligations in this regard. Our marketing and distribution arrangement with Esteve may not be successful, and, as a result, we may not receive any revenues from it. Also, we may not be able to enter into marketing and sales agreements for Surfaxin on acceptable terms, if at all, in territories not covered by the Esteve agreement, or for any of our other 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. Our operating plans require that expenditures will only be committed if we achieve important development and regulatory milestones and have the necessary working capital resources. Therefore, our existing capital will allow us to continue operations into 2009. 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 financing arrangements, if available. In some cases, we may elect to develop products on our own instead of entering into collaboration arrangements, which would increase our cash requirements for research and development.

We have not entered into arrangements to obtain any additional financing, except for the Committed Equity Financing Facility that we entered with Kingsbridge in April 2006 (the 2006 CEFF), the Committed Equity Financing Facility that we entered with Kingsbridge on May 22, 2008 (the 2008 CEFF), our loan with PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), the strategic investment group of Quintiles Transnational Corp., and our equipment financing facility with GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.) (GE). Any future financing could be on unattractive terms or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Furthermore, if the market price of our common stock were to decline, we could cease to meet the financial requirements to maintain the listing of our securities on The Nasdaq Global Market.

If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations. See also "Risk Factors – Our Committed Equity Financing Facilities may have a dilutive impact on our stockholders."

We continue to consider multiple strategic alternatives, including, but not limited to potential additional financings as well as potential business alliances, commercial and development partnerships and other similar opportunities, although we cannot assure you that we will take any further specific actions or enter into any transactions.

The terms of our indebtedness may impair our ability to conduct our business.

Our capital requirements are funded in part by an $8.5 million loan with PharmaBio, which is secured by substantially all of our assets and contains a number of covenants and restrictions that, with certain exceptions, restricts our ability to, among other things, incur additional indebtedness, borrow money or issue guarantees, use assets as security in other transactions, and sell assets to other companies. We may not be able to engage in these types of transactions, even if we believe that a specific transaction would be in our best interests. Moreover, our ability to comply with these restrictions could be affected by events outside our control. A breach of any of these restrictions could result in a default under the PharmaBio loan documents. If a default were to occur, PharmaBio would have the right to declare all borrowings to be immediately due and payable. If we are unable to pay when due amounts owed to PharmaBio, whether at maturity or in connection with acceleration of the loan following a default, PharmaBio would have the right to proceed against the collateral securing the indebtedness.

We have financed the acquisition of personal property, machinery and equipment through a $12.5 million equipment financing facility with GE under a Credit and Security Agreement that we entered with GE in May 2007. Our ability to draw under this facility expired in May 2008; however, we and GE recently agreed to extend this facility for six months into November 2008 to finance capital expenditure of up to $300,000, which represents our anticipated capital requirements for this period. If we require additional funds to support our activities during this period, as well as after this facility expires, there can be no assurance that GE or any other lender will be willing to provide us funding to support our capital programs.

In addition, the aggregate amount of our indebtedness may adversely affect our financial condition, limit our operational and financing flexibility and negatively impact our business.

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

The issuance of shares of our common stock under the 2006 CEFF and the 2008 CEFF (the CEFFs) 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 CEFFs, we will issue shares of our common stock to Kingsbridge at a discount (6% to 10% for the 2006 CEFF and 6% to 12% for the 2008 CEFF) to the daily volume weighted average price of our common stock during the eight trading-day period after we access the CEFF. Issuing shares at a discount will further dilute the interests of other stockholders.

To the extent that Kingsbridge sells to third parties the shares of our common stock that we issue to Kingsbridge under the CEFFs, 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.

If we are unable to meet the conditions provided under the CEFFs, 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 CEFFs. Kingsbridge has the right under certain circumstances to terminate the CEFFs, including in the event of a material adverse event. In addition, even if we meet all conditions provided under the CEFFs, we are dependent upon the financial ability of Kingsbridge to perform its obligations and purchase shares of our common stock under the CEFFs. Any inability on our part to use at least one of the CEFFs or any failure by Kingsbridge to perform its obligations under the CEFFs 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;
- patient adverse reactions to drug 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;
- changes in the United States or foreign political environment and the passage of laws, including tax, environmental or other laws, affecting the product development business;
- 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” or elsewhere in this Annual Report on Form 10-K or our other publics filings.

Our common stock is listed for quotation on The Nasdaq Global Market. During the 12 months ended June 3, 2008, the price of our common stock ranged from $1.29 to $3.58. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12 months ended June 3, 2008, the average daily trading volume in our common stock was approximately 1,017,594 shares and the average number of transactions per day was approximately2,576. The variability of our average volume and 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. We recently won dismissal of such an action, which was brought against us and certain of our former and current executive officers. Even if they or other actions that we may face in the future are ultimately determined to be meritless or unsuccessful, such actions involve substantial costs and a diversion of management attention and resources, which could negatively impact our business.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our stock incentive plans and upon the exercise of outstanding securities exercisable for shares of our common stock, could result in substantial additional dilution of our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

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 June 3, 2008, we had 96,693,377 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 $24.8 million is remaining. We may issue securities pursuant to this shelf registration statement from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

Additionally, there are (i) 375,000 shares of our common stock that are currently reserved for issuance with respect to the Class B Investor Warrant, (ii) approximately 5.2 million shares of our common stock that are currently reserved for issuance under the 2006 CEFF, including 490,000 shares reserved for issuance with respect to the Class C Investor Warrant issued to Kingsbridge in connection with the 2006 CEFF, and (iii) approximately 19.33 million shares of our common stock that are currently reserved for issuance under the new 2008 CEFF with Kingsbridge dated May 22, 2008, and 825,000 shares of our common stock reserved for issuance with respect to the Warrant that we issued to Kingsbridge in connection with the new 2008 CEFF. See “Risk Factors: Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.”

As of June 3, 2008, 18,631,821 shares of our common stock are reserved for issuance pursuant to our equity incentive plans (including 13,880,283 shares underlying outstanding stock options and 55,913 shares underlying unvested restricted stock awards), 7,164,196 shares of our common stock are reserved for issuance upon exercise of outstanding warrants, and 169,756 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 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 March 31, 2008, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 17% of the issued and outstanding shares of our common stock. For the purpose of computing this amount, an affiliated entity includes any entity that is known to us to be the beneficial owner of more than five percent of our issued and outstanding common stock. 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 technology platform is based solely on the scientific rationale of using our precision-engineered surfactant technology 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 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 (USPTO) has not adopted a consistent policy regarding the breadth of claims that it will allow 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 appear to be patentable.

Even if we obtain patents to protect our products, those patents may not be sufficiently broad or they may expire and others could then 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 USPTO 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 USPTO or foreign patent office issuing patents. In addition, 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, even if the USPTO or foreign patent offices were to 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 us any protection against competitors.

The patents that we hold also have a limited life. We have licensed a series of patents from Johnson & Johnson and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation (Ortho Pharmaceutical), and from PM USA and PMPSA, which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. These patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017 or, in some cases, possibly later. For our aerosolized SRT, we hold exclusive licenses in the United States and outside the United States to PM USA's capillary aerosolization technology for use with pulmonary surfactants for all respiratory diseases. Our exclusive license in the United States also extends to other drugs to treat specified target indications in specified target populations. The capillary aerosolization technology patents expire on various dates beginning in May 2016 and ending in 2022, 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 enhanced or additional products or processes that will be patentable under patent law and, if we do enhance or develop additional products that we believe are patentable, 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 depends upon our ability to operate our business without infringing the patents or violating the proprietary rights of others. The USPTO keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine in advance what inventions third parties may claim in their pending patent applications. We may need to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others through legal proceedings, which would be costly, unpredictable and time consuming. Even in proceedings where the outcome is favorable to us, they would likely divert substantial resources, including management time, from our other activities. Moreover, any adverse determination could subject us to significant liability or require us to seek licenses that third parties might not grant to us or might only grant at rates that diminish or deplete the profitability of our products. An adverse determination could also require us to alter our products or processes or cease altogether any product sales or related research and development activities.

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, PM USA and PMPSA. 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 our confidential information to third parties, as well as agreements that provide for disclosure and assignment to us of all rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, such agreements can be difficult and costly to enforce. Although we generally seek to enter into these types of agreements with our consultants, advisors and research collaborators, to the extent that such parties apply or independently develop intellectual property in connection with any of our projects, disputes may arise concerning allocation of the related proprietary rights. If a dispute were to arise, enforcement of our rights could be costly and the result unpredictable. In addition, we also rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our employees, consultants, advisors or others.

Despite the protective measures we employ, we still face the risk that:

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

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, Robert J. Capetola, Ph.D., 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.

Following receipt of the second Approvable Letter and the occurrence of the process validation stability failures in April 2006, we reduced our staff levels by approximately 50 people and reorganized our corporate structure. To retain and provide incentives to our key executives and certain officers, in 2006, we entered into amended and new employment agreements that generally include provisions such as a stated term, enhanced severance benefits in the event of a change of control and equity incentives in the form of stock and option grants. As of February 29, 2008, we have employment agreements with 13 officers, three of which expire in May 2010 and the remainder in December 2008. Each employment agreement provides that its term shall automatically be extended for one additional year, unless at least 90 days prior to the renewal date either party gives notice that it does not wish to extend the agreement. 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 may 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.

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 and we may incur substantial costs.

The clinical testing, marketing and use of our products exposes us to product liability claims if the use or misuse of our 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 coverage of up to $10 million per occurrence and $10 million in the aggregate. 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, including by insurers licensed in countries where we conduct our clinical trials, before initiating clinical trials. We expect to obtain product liability insurance coverage before commercializing any of our product candidates; however, such insurance is expensive and may not be available when we need it.

In the future, we may not be able to obtain adequate insurance, with acceptable limits and retentions, at an acceptable cost. Any product liability claim, even one that is within the limits of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect the availability or cost of insurance generally and our cash available for other purposes, such as research and development. In addition, such claims could result in:

- uninsured expenses related to defense or payment of substantial monetary awards to claimants;
- a decrease in demand for our product candidates;
- damage to our reputation; and
- an inability to complete clinical trial programs or to commercialize our product candidates, if approved.

Moreover, the existence of a product liability claim could affect the market price of our common stock.

Our corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations affecting our activities in the jurisdictions in which we may sell our products, if approved, and a failure to comply with such regulations or prevail in litigation related to noncompliance could harm our business.

Many of our activities, including the research, development, manufacture, sale and marketing of our products, are subject to extensive laws and regulation, including without limitation, health care "fraud and abuse" laws, such as the federal false claims act, the federal anti-kickback statute, and other state and federal laws and regulations. We have developed and implemented a corporate compliance policy and oversight program based upon what we understand to be current industry best practices, but we cannot assure you that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such investigations, actions or lawsuits are instituted against us, and if we are not successful in defending or disposing of them without liability, such investigations, actions or lawsuits could result in the imposition of significant fines or other sanctions and could otherwise have a significant impact on our business.

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 payers, which include governmental health administration authorities, managed care providers and private health insurers. Third party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services. Moreover, the current political environment in the United States and abroad may result in the passage of significant legislation that could, among other things, restructure the markets in which we operate and restrict pricing strategies of drug development companies. If, for example, price restrictions were placed on the distribution of drugs such as our SRT, we may be forced to curtail development of our pipeline products and this could have a material adverse effect on our business, results of operations and financial condition. Even if we succeed in commercializing our SRT, uncertainties regarding health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in quantities or at prices that will enable us to achieve profitability.

To obtain reimbursement from a third party payer, it must determine that our drug product is a covered benefit under its health plan, which is likely to require a determination that our product is:

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining a determination that a product is a covered benefit may be a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data about our products to each payer. We may not be able to provide sufficient data to gain coverage.

Even when a payer determines that a product is covered, the payer may impose limitations that preclude payment for some uses that are approved by the FDA or other regulatory authorities. Moreover, coverage does not imply that any product will be covered in all cases or that reimbursement will be available at a rate that would permit a health care provider to cover its costs of using our product.

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

Provisions of our Restated Certificate of Incorporation, as amended, our Shareholder 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 Shareholder 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 Shareholder 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. 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 naming as defendants the Company and certain of its current and former executive officers and directors. The derivative actions were consolidated under the caption “In re: Discovery Laboratories Securities Litigation” and the class actions were consolidated under the caption “In re: Discovery Laboratories Securities Litigation”. The District Court granted our motions to dismiss two Consolidated Amended Complaints in each proceeding. The derivative actions were not appealed and that matter is concluded. In April 2008, the Third Circuit Court of Appeals affirmed the District Court’s dismissal of the second Consolidated Amended Complaint in the class actions for the reasons set forth in the District Court opinion, and this matter is now concluded.

Even if actions such as these are found to be without merit, the potential impact of such 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 any future proceeding 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 and proceedings arising in the ordinary course of business, including in connection with the conduct of clinical trials and the termination of certain pre-launch commercial programs following the April 2006 manufacturing issues. Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. Although we believe such claims are unlikely to have a material adverse effect on our financial condition or results of operations, it is impossible to predict with certainty the eventual outcome of such claims and there can be no assurance that we will be successful in any proceeding to which we may be a party.

In addition, as the USPTO keeps United States patent applications confidential while the applications are pending, 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 USPTO, 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 and Section 21E of the Securities Exchange Act of 1934 (Exchange Act). 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. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition; plans regarding the May 2008 Approvable Letter that we received from the FDA for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome in premature infants; 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 regarding strategic alliances and collaboration arrangements with pharmaceutical companies and others to develop, manufacture and market our drug products; research and development of particular drug products, technologies and aerosolization drug devices; the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties that 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 we may not be able to timely respond to the Approvable Letter that we recently received for Surfaxin and that any response that we do file will not satisfy the FDA;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, including our New Drug Application (NDA) for Surfaxin, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;
- risks relating to the rigorous regulatory approval processes, including pre-NDA activities, required for approval of any drug or medical device products that we may develop, independently, with development partners or pursuant to collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- risks relating to our research and development activities, which involve time-consuming and expensive pre-clinical studies, multi-phase clinical trials and other studies and other efforts, and which may be subject to potentially significant delays or regulatory holds, or fail;
- the risk that we, our contract manufacturers or any of our materials suppliers encounter problems manufacturing our products or drug substances on a timely basis or in an amount sufficient to meet demand;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;
- risks relating to the ability of our development partners and third-party suppliers of materials, drug substances and aerosolization systems and related components to timely provide us with adequate supplies and expertise to support development and manufacture of drug product and aerosolization systems for initiation and completion of our clinical studies, and, if approved, commercialization of our drug and combination drug-device products;
- the risk that we may not successfully and profitably market our products;
- the risk that, even if approved, we may be unable, for reasons related to market conditions, the competitive landscape or otherwise, to successfully launch and market our products;

- risks relating to our ability to develop a successful sales and marketing organization to market Surfaxin, if approved, and our other product candidates, in a timely manner, if at all, and that we or our marketing and advertising consultants will not succeed in developing market awareness of our products;
- the risk that we or our development partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;
- the risk that our product candidates will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;
- the risk that we may not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT);
- the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;
- risks relating to reimbursement and health care reform;
- risks that financial market conditions may change, additional financings could result in equity dilution, or we will be unable to maintain The Nasdaq Global Market listing requirements, causing the price of our shares of common stock to decline;
- the risk that we may be unable to maintain and protect the patents and licenses related to our SRT; other companies may develop competing therapies and/or technologies or health care reform may adversely affect us;
- the risk that we may become involved in securities, product liability and other litigation;
- other risks and uncertainties detailed in “Risk Factors” and in the documents incorporated by reference in this prospectus.

Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical companies face considerable challenges in marketing and distributing their products, and may never become profitable.

Except to the extent required by applicable laws, rules and regulations, we do not undertake any obligation or duty 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.

USE OF PROCEEDS

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

SELLING STOCKHOLDER

This prospectus relates to the possible resale by the selling stockholder, Kingsbridge, of shares of common stock that we may issue pursuant to the Common Stock Purchase Agreement we entered into with Kingsbridge on May 22, 2008, or upon exercise of the Warrant we issued to Kingsbridge. We are filing the registration statement of which this prospectus is a part pursuant to the provisions of the Registration Rights Agreement we entered into with Kingsbridge on May 22, 2008.

The selling stockholder may from time to time offer and sell pursuant to this prospectus any or all of the shares that it acquires under the Common Stock Purchase Agreement or upon exercise of the Warrant.

The following table presents information regarding Kingsbridge and the shares that it may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of May 22, 2008. As used in this prospectus, the term “selling stockholder” includes Kingsbridge and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge or other non-sale related transfer. The number of shares in the column “Number of Shares Being Offered” represents all of the shares that the selling stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. The percentage of shares beneficially owned before the offering is based both on 96,688,377 shares of our common stock actually outstanding as of May 22, 2008 and on the assumption that all shares of common stock issuable to Kingsbridge under the Common Stock Purchase Agreement or upon exercise of the Warrant are outstanding as of that date.

Name	Total Number of Shares of Common Stock Beneficially Owned	Percentage Beneficially Owned Before Offering	Number of Shares Being Offered	Number of Shares to be Owned after this Offering	Percentage to be Beneficially Owned after this Offering
Kingsbridge Capital Limited (1)	21,018,000(2)	21.7%	20,153,000	865,000	*

(1) The address of Kingsbridge is Kingsbridge Capital Limited, PO Box 1075, Elizabeth House, 9 Castle Street, St. Helier, Jersey, JE42QP, Channel Islands.

(2) Consists of (a) 19,328,000 shares of common stock issuable under the Common Stock Purchase Agreement we entered into with Kingsbridge on May 22, 2008, (b) 825,000 shares of common stock issuable upon exercise of the Warrant, which warrant is not exercisable before November 22, 2008 (c) 490,000 shares of common stock issuable upon exercise of the Warrant and (d) 375,000 shares of common stock issuable upon exercise of the Class B Investor Warrant issued to Kingsbridge on July 7, 2004. For the purposes hereof, we assume the issuance of all shares under the Common Stock Purchase Agreement and upon exercise of the Warrant. We have been advised that Adam Gurney, Maria O'Donoghue and Tony Gardner-Hillman have shared voting and investment control of the securities held by Kingsbridge, and that Kingsbridge does not accept third party investments. Accordingly, Mr. Gurney, Ms. O'Donoghue and Mr. Gardner-Hillman beneficially own the shares of our common stock owned by Kingsbridge.

PLAN OF DISTRIBUTION

We are registering 20,153,000 shares of common stock under this prospectus on behalf of Kingsbridge. Except as described below, to our knowledge, the selling stockholder has not entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the shares of common stock offered hereby, nor, except as described below, do we know the identity of the brokers or market makers that will participate in the sale of the shares.

The selling stockholder may decide not to sell any shares. The selling stockholder may from time to time offer some or all of the shares of common stock through brokers, dealers or agents who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder and/or the purchasers of the shares of common stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the selling stockholder may arrange for other broker-dealers to participate. Kingsbridge is an "underwriter" within the meaning of the Securities Act. Any brokers, dealers or agents who participate in the distribution of the shares of common stock may also be deemed to be "underwriters," and any profits on the sale of the shares of common stock by them and any discounts, commissions or concessions received by any such brokers, dealers or agents may be deemed to be underwriting discounts and commissions under the Securities Act. Kingsbridge has advised us that it may effect resales of our common stock through any one or more registered broker-dealers. To the extent the selling stockholder may be deemed to be an underwriter, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made over The Nasdaq Global Market , on the over-the-counter market, otherwise or in a combination of such methods of sale, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares of common stock may be sold according to one or more of the following methods:

- a block trade in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus;
- an over-the-counter distribution in accordance with NASDAQ Stock Market LLC or Financial Industry Regulatory Authority rules;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- privately negotiated transactions;
- a combination of such methods of sale; and
- any other method permitted pursuant to applicable law.

Any shares covered by this prospectus which qualify for sale pursuant to Rule 144 of the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. In addition, the selling stockholder may transfer the shares by other means not described in this prospectus.

Any broker-dealer participating in such transactions as agent may receive commissions from Kingsbridge (and, if they act as agent for the purchaser of such shares, from such purchaser). Broker-dealers may agree with Kingsbridge to sell a specified number of shares at a stipulated price per share, and, to the extent such a broker-dealer is unable to do so acting as agent for Kingsbridge, to purchase as principal any unsold shares at the price required to fulfill the broker-dealer commitment to Kingsbridge. Broker-dealers who acquire shares as principal may thereafter resell such shares from time to time in transactions (which may involve crosses and block transactions and which may involve sales to and through other broker-dealers, including transactions of the nature described above) on The Nasdaq Global Market, on the over-the-counter market, in privately-negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such shares commissions computed as described above. To the extent required under the Securities Act, an amendment to this prospectus, or a supplemental prospectus may be filed, disclosing:

- the name of any such broker-dealers;
- the number of shares involved;
- the price at which such shares are to be sold;
- the commission paid or discounts or concessions allowed to such broker-dealers, where applicable;
- that such broker-dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented; and
- other facts material to the transaction.

Underwriters and purchasers that are deemed underwriters under the Securities Act may engage in transactions that stabilize maintain or otherwise affect the price of the securities, including the entry of stabilizing bids or syndicate covering transactions or the imposition of penalty bids. Kingsbridge and any other persons participating in the sale or distribution of the shares will be subject to the applicable provisions of the Exchange Act and the rules and regulations thereunder including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of, purchases by the selling stockholder or other persons or entities. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distributions, subject to special exceptions or exemptions. Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making and certain other activities with respect to those securities. In addition, the anti-manipulation rules under the Exchange Act may apply to sales of the securities in the market. All of these limitations may affect the marketability of the shares and the ability of any person to engage in market-making activities with respect to the securities.

We have agreed to pay the expenses of registering the shares of common stock under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees, as well as certain fees of counsel for the selling stockholder incurred in the preparation of the CEFF agreements and the registration statement of which this prospectus forms a part. The selling stockholder will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as transfer taxes and certain other expenses associated with the sale of securities.

Under the terms of the Common Stock Purchase Agreement and the Registration Rights Agreement, we have agreed to indemnify the selling stockholder and certain other persons against certain liabilities in connection with the offering of the shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute toward amounts required to be paid in respect of such liabilities.

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 stockholder 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 Restated Certificate of Incorporation and our By-Laws, and not this summary, which define 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 June 3, 2008, there were 96,693,377 shares of common stock outstanding, which does not include:

- 13,880,283 shares of common stock issuable upon exercise of options outstanding as of June 3, 2008, at a weighted average exercise price of $4.23 per share;
- 7,164,196 shares of common stock issuable upon exercise of warrants outstanding as of June 3, 2008, at a weighted average exercise price of $4.71;
- 5,170,024 shares of common stock reserved for potential future issuance pursuant to the 2006 CEFF.
- an indeterminate number of shares of common stock issuable under our shelf registration statement on Form S-3 (No. 333-128929) dated October 11, 2005;
- 55,913 shares of common stock issuable upon the vesting of restricted stock awards outstanding as of June 3, 2008;
- 4,695,625 shares of common stock available for future grant under our 2007 Long-Term Incentive Plan; and
- 169,756 shares of common stock reserved for potential future issuance pursuant to a 401(k) Plan, as of June 3, 2008.

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 provisions of our Shareholder Rights Agreement, dated as of February 6, 2004.

On February 6, 2004, our Board of Directors adopted a Shareholder Rights Agreement (the 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 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

The consolidated financial statements of Discovery incorporated by reference in Discovery Laboratories, Inc. Annual Report (Form 10-K) for the year ended December 31, 2007, and the effectiveness of Discovery's internal control over financial reporting as of December 31, 2007 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their reports thereon, incorporated by reference therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firm 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.

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 or contact 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, 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.

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, 2007, filed on March 14, 2008;

2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed on May 9, 2008;

3. Our Current Reports on Form 8-K filed with the SEC on January 3, 2008 and February 15, 2008 (excluding the matters in Item 2.02 and Exhibit 99.1 therein, which are not incorporated by reference herein), April 3, 2008, April 11, 2008, May 2, 2008, May 8, 2008(excluding the matters in Item 2.02 and Exhibit 99.1 therein, which are not incorporated by reference herein), May 19, 2008, May 28, 2008, May 29, 2008, and June 2, 2008;

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.

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 of the initial registration statement 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.

You may request a copy of these filings, at no cost, by sending an e-mail to ir@DiscoveryLabs.com and requesting any one or more of such filings or by contacting John G. Cooper, our 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.