

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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2005

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3171943

(I.R.S. Employer Identification No.)

2600 Kelly Road, Suite 100

Warrington, PA 18976

(Address of principal executive offices)

18976

(Zip Code)

(215) 488-9300

(Registrants' telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 2, 2005, 57,452,575 shares of common stock, par value \$0.001 per share, were outstanding.

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Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Discovery Laboratories, Inc. (“Discovery”), and its wholly-owned, presently inactive subsidiary, Acute Therapeutics, Inc.

FORWARD LOOKING STATEMENTS

The statements set forth under Part I, Item 2: “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, including those incorporated by reference herein, which are not historical, including, without limitation, statements concerning our research and development programs and clinical trials, the possibility of submitting regulatory filings for our products under development, the seeking of collaboration arrangements with pharmaceutical companies or others to develop, manufacture and market products, the research and development of particular compounds and technologies and the period of time for which our existing resources will enable us to fund our operations, constitute “Forward Looking Statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to: risk that financial conditions may change; risks relating to the progress of our research and development (including the results of clinical trials being conducted by us and the risk that our lead product candidate, Surfaxin[®], or other drug candidates will not prove to be safe or useful for the treatment of certain indications); the risk that we will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies); risk that we will not be able to develop a successful sales and marketing organization in a timely manner, if at all; risk that our internal sales and marketing organization will not succeed in developing market awareness of our products; risk that our internal sales and marketing organization will not be able to attract or maintain qualified personnel; delays in the FDA’s or other health regulatory authorities’ approval or potential rejection of any applications we file, including the New Drug Application (NDA) we filed in April 2004 and the Marketing Approval Application (MAA) we submitted in October 2004; risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product; risks relating to the ability of our third party contract manufacturers to provide us with adequate supplies of drug substance and drug products for completion of any of our clinical studies or commercialization; risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of our clinical studies, and risks relating to the development of competing therapies and/or technologies by other companies; and the other risks and uncertainties detailed in Part I, Item 2: “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business,” and in the documents incorporated by reference in this report. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval.

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

PART I - FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****DISCOVERY LABORATORIES, INC. AND SUBSIDIARY****Consolidated Balance Sheets***(In thousands, except per share data)*

| | September 30, 2005 | December 31, 2004 |
|--|-----------------------|----------------------|
| | (Unaudited) | |
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 41,249 | \$ 29,264 |
| Restricted cash | 647 | 646 |
| Available-for-sale marketable securities | 8,444 | 2,744 |
| Note receivable, current portion | 3 | 3 |
| Prepaid expenses and other current assets | 720 | 685 |
| Total Current Assets | 51,063 | 33,342 |
| Property and equipment, net of accumulated depreciation | 4,129 | 4,063 |
| Note receivable, non-current portion | 188 | 190 |
| Other assets | 31 | 42 |
| Total Assets | \$ 55,411 | \$ 37,637 |
| LIABILITIES & STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | \$ 6,869 | \$ 7,969 |
| Capitalized leases, current portion | 1,009 | 854 |
| Total Current Liabilities | 7,878 | 8,823 |
| Deferred revenue | 29 | 134 |
| Credit facility, non-current portion | 8,500 | 5,929 |
| Capitalized leases, non-current portion | 1,587 | 1,654 |
| Total Liabilities | 17,994 | 16,540 |
| Stockholders' Equity: | | |
| Common Stock (\$0.001 par value; 180,000 and 80,000 authorized; 57,104 and 48,747 issued, 56,791 and 48,434 outstanding at September 30, 2005 and December 31, 2004, respectively) | 57 | 49 |
| Additional paid-in capital | 213,316 | 167,627 |
| Unearned portion of compensatory stock options | (288) | (461) |
| Accumulated deficit | (172,609) | (143,061) |
| Treasury stock (at cost; 313 shares) | (3,054) | (3,054) |
| Accumulated other comprehensive loss | (5) | (3) |
| Total Stockholders' Equity | 37,417 | 21,097 |
| Total Liabilities & Stockholders' Equity | \$ 55,411 | \$ 37,637 |

PART I - FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****DISCOVERY LABORATORIES, INC. AND SUBSIDIARY**

Consolidated Statements of Operations

(Unaudited)

(In thousands, except per share data)

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|-------------------|--------------------|--------------------|
| | September 30, | | September 30, | |
| | 2005 | 2004 | 2005 | 2004 |
| Revenues: | | | | |
| Contracts and Grants | \$ 20 | \$ 236 | \$ 105 | \$ 1,075 |
| Expenses: | | | | |
| Research & Development | 5,676 | 5,673 | 16,660 | 18,757 |
| General & Administrative | 4,817 | 2,908 | 13,182 | 8,363 |
| Total Expenses | 10,493 | 8,581 | 29,842 | 27,120 |
| Operating Loss | (10,473) | (8,345) | (29,737) | (26,045) |
| Other income and (expense): | | | | |
| Interest and other income | 328 | 125 | 884 | 277 |
| Interest expense | (261) | (162) | (695) | (383) |
| Net Loss | <u>\$ (10,406)</u> | <u>\$ (8,382)</u> | <u>\$ (29,548)</u> | <u>\$ (26,151)</u> |
| Net loss per common share - basic and diluted | \$ (0.19) | \$ (0.18) | \$ (0.56) | \$ (0.57) |
| Weighted average number of common shares outstanding - basic and diluted | 54,476 | 46,988 | 52,844 | 45,659 |

PART I - FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****DISCOVERY LABORATORIES, INC. AND SUBSIDIARY****Consolidated Statements of Cash Flows**

(Unaudited)

(In thousands)

| | Nine Months Ended | |
|---|--------------------------|------------------|
| | September 30, | |
| | 2005 | 2004 |
| Cash flows from operating activities: | | |
| Net loss | \$ (29,548) | \$ (26,151) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 585 | 614 |
| Compensatory stock options expense / 401k match | 468 | 647 |
| Loss on disposal of property and equipment | 16 | -- |
| Changes in: | | |
| Prepaid expenses and other current assets | (35) | (766) |
| Accounts payable and accrued expenses | (1,100) | 8 |
| Note receivable and other assets | 13 | (72) |
| Deferred revenue | (105) | (403) |
| Net cash used in operating activities | <u>(29,706)</u> | <u>(26,123)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (667) | (894) |
| Restricted cash | (1) | (650) |
| Purchases of marketable securities | (30,110) | (18,344) |
| Proceeds from sales or maturity of marketable securities | 24,408 | 7,444 |
| Net cash used in investing activities | <u>(6,370)</u> | <u>(12,444)</u> |
| Cash flows from financing activities: | | |
| Proceeds from issuance of securities, net of expenses | 45,402 | 28,940 |
| Proceeds from credit facility | 2,571 | 3,247 |
| Proceeds from capital lease facility | 757 | 1,237 |
| Purchase of treasury stock | -- | (1,765) |
| Principal payments under capital lease obligation | (669) | (354) |
| Net cash provided by financing activities | <u>48,061</u> | <u>31,305</u> |
| Net increase / (decrease) in cash and cash equivalents | 11,985 | (7,262) |
| Cash and cash equivalents - beginning of period | 29,264 | 29,422 |
| Cash and cash equivalents - end of period | <u>\$ 41,249</u> | <u>\$ 22,160</u> |
| Supplementary disclosure of cash flows information: | | |
| Interest paid | \$ 612 | \$ 101 |
| Non-cash transactions: | | |
| Class H warrants issued/revalued | -- | (48) |
| Deferred debt issuance costs | -- | 1,523 |
| Unrealized loss on marketable securities | (2) | (5) |

Notes to Consolidated Financial Statements (unaudited)

Note 1 - The Company and Basis of Presentation

The Company

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

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. Our lead product, Surfaxin[®] (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) and is under review for approval in Europe by the European Medical Evaluation Agency (EMA). Surfaxin is also being developed for the treatment of Chronic Lung Disease (CLD, also known as Bronchopulmonary Dysplasia) in premature infants. In addition, we are developing Aerosurf[™], aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for Neonatal Respiratory Failures.

Our SRT technology is also being developed to address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings. We are conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and are also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disorder (COPD), and other respiratory conditions.

With the goal of becoming a fully integrated biotechnology company, we are implementing a long-term business strategy which includes: (i) investing in manufacturing capabilities for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States, Europe and other markets; (ii) building our own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU; (iii) securing aerosol generating technology and engineering capabilities through a corporate partnership for our aerosol SRT pipeline programs, including Aerosurf; and (iv) securing corporate partnerships for the development and potential commercialization of SRT, including Surfaxin, in Europe and the rest of the world.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and nine month period ended September 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2004.

All of our current products under development are subject to license agreements that will require the payment of future royalties.

Certain prior period balances have been reclassified to conform to the current period presentation.

Note 2 - Net Loss Per Share

Net loss per share is computed based on the weighted average number of common shares outstanding for the periods. Common shares issuable upon the exercise of options and warrants are not included in the calculation of the net loss per share as their effect would be anti-dilutive.

Note 3 - Stock Based Employee Compensation

The Financial Accounting Standards Board (FASB) has issued Statement of Financial Accounting Standards (SFAS) No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure". SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition to a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS 123 to require prominent disclosure in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on the reported results. We continue to account for our stock option plans in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Options Issued to Employees" and, accordingly, recognize compensation expense for the difference between the fair value of the underlying common stock and the exercise price of the options at the date of grant. The effect of applying SFAS No. 148 on pro forma net loss is not necessarily representative of the effects on reported net income or loss for future years due to, among other things, (i) the vesting period of the stock options and (ii) the fair value of additional stock options in future years. Had compensation costs for our stock option plans been determined based upon the fair value of the options at the grant date of awards under the plans consistent with the methodology prescribed under SFAS No. 148, the pro forma net loss for the three and nine months ended September 30, 2005 and 2004 would have been as follows:

| <i>(in thousands, except per shares data)</i> | Three Months Ended | | Nine Months Ended | |
|--|--------------------|------------|-------------------|-------------|
| | September 30, | | September 30, | |
| | 2005 | 2004 | 2005 | 2004 |
| Net loss, as reported | \$ (10,406) | \$ (8,382) | \$ (29,548) | \$ (26,151) |
| Additional stock-based employee compensation | \$ (1,163) | \$ (956) | \$ (5,796) | \$ (3,378) |
| Pro forma net loss | \$ (11,569) | \$ (9,338) | \$ (35,344) | \$ (29,529) |
| Pro forma net loss per share | \$ (0.21) | \$ (0.20) | \$ (0.67) | \$ (0.65) |
| Net loss per common share - basic and diluted, as reported | \$ (0.19) | \$ (0.18) | \$ (0.56) | \$ (0.57) |

In December 2004, the FASB issued SFAS No. 123 (revised 2004) "Share-Based Payment". SFAS 123(R) requires stock-based employee compensation to be measured based on the grant-date fair value of the award and the cost to be recognized over the period during which an employee is required to provide service in exchange for the award. SFAS 123(R) eliminates the alternative use of APB No. 25's intrinsic value method of accounting for awards that was provided in SFAS 123 as originally issued. We are in the process of evaluating the impact of this standard on our financial statements. We will apply the "modified prospective" transition method and implement the provisions of SFAS No. 123(R) beginning in the first quarter of 2006.

Note 4 - Comprehensive Loss

Total comprehensive loss was \$10.4 million and \$29.6 million for the three and nine months ended September 30, 2005, respectively, and \$8.4 million and \$26.2 million for the three and nine months ended September 30, 2004. Total comprehensive loss consists of the net loss and unrealized gains and losses on marketable securities.

Note 5 - Restricted Cash

There are cash balances that are restricted as to use and we disclose such amounts separately on our balance sheets. The primary component of Restricted Cash is a security deposit in the amount of \$600,000 in the form of a letter of credit related to the lease agreement dated May 26, 2004 for office space in Bucks County, Pennsylvania. The letter of credit is secured by cash and is recorded in our balance sheets as "Restricted Cash." Beginning in March 2008, the security deposit and the letter of credit will be reduced to \$400,000 and will remain in effect through the remainder of the lease term. Subject to certain conditions, upon expiration of the lease in November 2009, the letter of credit will expire.

Note 6 - Note Receivable

Note receivable pertains to a \$200,000, 7% per annum mortgagor's note due from one of our executive officers. This note is secured by a mortgage agreement dated July 24, 2001. The note calls for monthly payments of principal and interest over a 360-month period. The principal balance outstanding at September 30, 2005 and December 31, 2004 was approximately \$191,000 and \$193,000, respectively.

Note 7 - Treasury Stock

Occasionally, certain members of our management and certain consultants, pursuant to terms set forth in our Amended and Restated 1998 Stock Incentive Plan, tender shares of common stock held by such persons in lieu of cash for payment for the exercise of certain stock options previously granted to such parties. These shares are accounted for as treasury stock. There were no such shares tendered during the nine months ended September 30, 2005.

Note 8 - Subsequent Events

Sale of Common Stock

On November 2, 2005, we sold 650,000 shares of our common stock to Laboratorios del Dr. Esteve S.A. (Esteve), at a price per share of \$6.88, for aggregate proceeds of approximately \$4.5 million. The shares were issued pursuant to a registration statement on Form S-3MEF filed with the Securities and Exchange Commission (SEC) on February 17, 2005.

Universal Shelf Registration Statement

On October 11, 2005, we filed a universal shelf registration statement on Form S-3 with the SEC for the proposed offering from time to time of up to \$100 million of our debt or equity securities. The universal shelf registration statement was declared effective by the SEC on October 24, 2005.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

"Management's Discussion and Analysis of Financial Condition and Results of Operations" should be read in connection with our Consolidated Financial Statements.

Overview

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

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. Our lead product, Surfaxin[®] (lucinactant), for the prevention of RDS in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the treatment of CLD (also known as Bronchopulmonary Dysplasia) in premature infants. In addition, we are developing Aerosurf[™], aerosolized SRT administered through nCPAP, for Neonatal Respiratory Failures.

Our SRT technology is also being developed to address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings. We are conducting a Phase 2 clinical trial to address ARDS in adults, and are also developing aerosol formulations of SRT to address ALI, asthma, COPD, and other respiratory conditions.

With the goal of becoming a fully integrated biotechnology company, we are implementing a long-term business strategy which includes: (i) investing in manufacturing capabilities for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States, Europe and other markets; (ii) building our own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU; (iii) securing aerosol generating technology and engineering capabilities through a corporate partnership for our aerosol SRT pipeline programs, including Aerosurf; and (iv) securing corporate partnerships for the development and potential commercialization of SRT, including Surfaxin, in Europe and the rest of the world.

In anticipation of the potential approval of Surfaxin for the prevention of RDS in premature infants in the United States and other global markets and to further the development of our SRT pipeline, we are presently implementing a business strategy which includes:

- (i) manufacturing for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States, Europe and other markets. We are investing in the further development and scale-up of the contract manufacturer of our SRT, Laureate Pharma, Inc. (Laureate), and securing additional manufacturing capabilities to meet production needs as they expand, including alternative contract manufacturers and acquiring our own manufacturing facility. In January 2005, the FDA issued an inspection report (FDA Form-483) to Laureate citing certain observations concerning Laureate's compliance with cGMPs in connection with the FDA's review of our New Drug Application (NDA) for Surfaxin for the prevention of RDS in premature infants. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. Certain quality systems and documentation control enhancements have been implemented by us and Laureate in response to the FDA's inspection report. Our previously submitted responses to the Approvable Letter have been accepted by the FDA as a complete response as of October 5, 2005. This date also marks the start of the six month review period during which the FDA expects to complete its review of our NDA for Surfaxin for the prevention of RDS in premature infants. We believe that the quality systems and documentation control enhancements that we have implemented jointly with Laureate to support our response to the FDA prepare us for the FDA's reinspection of Laureate's Totowa facility within the six month review cycle. Some pre-approval activities related to our Surfaxin manufacturing process, including process validation, have been completed, while certain reinspection activities are ongoing. Assuming that such corrective actions are adequate, we anticipate that our NDA will be approved in April 2006 and that the potential commercial launch of Surfaxin will occur in the second quarter of 2006; and
- (ii) building sales and marketing capabilities to execute the launch of Surfaxin in the United States, if approved. We are building our own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU and, as products are developed, to expand to critical care and hospital settings. This strategic initiative, led by the anticipated commercial launch of Surfaxin, is intended to allow us to manage and administer our own sales and marketing operation, establish a strong presence in the NICU and optimize company economics.

Since our inception, we have incurred significant losses and, as of September 30, 2005, had an accumulated deficit of \$172.6 million (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and manufacturing efforts (including raw material costs). We expense research and development costs as they are incurred. General and administrative expenses consist primarily of executive management, financial, business development, pre-launch commercialization sales and marketing, legal and general corporate activities and related expenses. See "Plan of Operations."

Historically, we have funded our operations with working capital provided principally through public and private equity financings and strategic collaborations. As of September 30, 2005, we had: (i) cash and investments of \$50.3 million, (ii) \$50.8 million available under our Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), subject to the terms and conditions of the CEFF, (iii) a \$9.0 million capital equipment lease financing arrangement with General Electric Capital Corporation (GECC), of which \$3.8 million has been drawn and, after giving effect to principal payments, \$2.6 million was outstanding, and (iv) a secured revolving credit facility of \$8.5 million with PharmaBio Development Inc. (PharmaBio), of which the entire amount was outstanding.

Research and Development

Research and development expenses for the three and nine months ended September 30, 2005 were \$5.7 million and \$16.7 million, respectively, and for the three and nine months ended September 30, 2004, were \$5.7 million and \$18.8 million, respectively. These costs are charged to operations as incurred and we track such costs by category rather than by project. Research and development costs consist primarily of expenses associated with research and pre-clinical operations, manufacturing development, clinical and regulatory operations and other direct clinical trials activities.

These cost categories typically include the following expenses:

Research and Pre-Clinical Operations

Research and pre-clinical operations reflect activities associated with research prior to the initiation of any potential human clinical trials. These activities predominantly represent projects associated with the development of aerosolized and other related formulations of our precision-engineered lung surfactant and engineering of aerosol delivery systems to potentially treat a range of respiratory disorders prevalent in the NICU and the hospital. Research and pre-clinical operations costs primarily reflect expenses incurred for personnel, consultants, facilities and research and development arrangements with collaborators.

Manufacturing Development

Manufacturing development primarily reflects costs incurred to prepare current good manufacturing procedures (cGMP) manufacturing capabilities in order to provide clinical and commercial scale drug supply. Manufacturing development activities include external contract manufacturing resources (as well as further development and scale-up of our current contract manufacturer of SRT, Laureate and securing additional manufacturing capabilities to meet production needs as they expand, including alternative contract manufacturers and acquiring our own manufacturing facility), personnel costs, depreciation and expenses associated with technology transfer, quality control and assurance activities and analytical services.

Unallocated Development -- Clinical and Regulatory Operations

Clinical and regulatory operations reflect the preparation, implementation and management of our clinical trial activities in accordance with current good clinical practices (cGCPs). Included in unallocated clinical development and regulatory operations are costs associated with personnel, supplies, facilities, fees to consultants and other related costs for clinical trial implementation and management, clinical quality control and regulatory compliance activities, data management and biostatistics.

Direct Expenses -- Clinical Trials

Direct expenses of clinical trials includes patient enrollment costs, external site costs, expense of clinical drug supply and external costs such as contract research consultant fees and expenses.

The following summarizes our research and development expenses by the foregoing categories for the three and nine months ended September 30, 2005 and 2004:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------------|------------------------------------|------------------|
| | 2005 | 2004 | 2005 | 2004 |
| <i>(in thousands)</i> | | | | |
| Research and Development Expenses: | | | | |
| Research and pre-clinical operations | \$ 448 | \$ 728 | \$ 1,803 | \$ 2,030 |
| Manufacturing development | 2,950 | 1,069 | 6,997 | 4,632 |
| Unallocated development - clinical and regulatory operations | 1,874 | 1,904 | 5,356 | 6,150 |
| Direct clinical trial expenses | 404 | 1,972 | 2,504 | 5,945 |
| Total Research and Development Expenses | \$ 5,676 | \$ 5,673 | \$ 16,660 | \$ 18,757 |

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimable. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Currently, none of our drug product candidates are available for commercial sale. All of our potential products are in regulatory review, clinical or pre-clinical development and the status and anticipated completion date of each of our lead SRT programs is discussed in "Plan of Operations." Successful completion of development of our SRT is contingent on numerous risks, uncertainties and other factors, which are described in detail in the section entitled "Risks Related to Our Business."

These factors include:

- Completion of pre-clinical and clinical trials of the product candidate with the scientific results that support further development and/or regulatory approval;
- Receipt of necessary regulatory approvals;
- Obtaining adequate supplies of surfactant raw materials on commercially reasonable terms;
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials;
- Performance of third-party collaborators on whom we rely for the commercialization and manufacture of Surfaxin;
- Timely resolution of certain cGMP-related matters at Laureate, the contract manufacturer for Surfaxin and certain other SRTs presently under development, including matters that were noted by the FDA in its inspectional report on FDA Form-483; and
- Obtaining manufacturing and sales and marketing capabilities for which we presently have limited resources.

As a result of the amount and nature of these factors, many of which are outside our control, 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 clinical supplies and material;
- Adverse medical events or side effects in treated patients;
- Lack of effectiveness of the product candidate being tested; and
- Lack of sufficient funds.

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our SRT products. If we do not obtain and maintain regulatory approval for our products, we will not generate any revenues from the sale of our products and our value, financial condition and results of operations will be substantially harmed.

Corporate Partnership Agreements

Quintiles Transnational Corp. and PharmaBio Development Inc.

In 2001, we entered into a commercialization agreement with Quintiles Transnational Corp. (Quintiles), and its strategic investment group affiliate, PharmaBio, to provide certain commercialization services in the United States for Surfaxin for the prevention of RDS in premature infants and the treatment of Meconium Aspiration Syndrome (MAS) in full-term infants.

In November 2004, we reached an agreement with Quintiles to restructure our business arrangements and terminate the commercialization agreement for Surfaxin in the United States. We now have full commercialization rights for Surfaxin in the United States. Pursuant to the restructuring, Quintiles is no longer obligated to provide any commercialization services and our obligation to pay a commission on net sales in the United States of Surfaxin for the prevention of RDS in premature infants and the treatment of MAS to Quintiles has been terminated.

In connection with our arrangement to regain full commercialization rights for Surfaxin, we issued warrants to PharmaBio to purchase 850,000 shares of common stock at an exercise price equal to \$7.19 per share. The warrants have a 10-year term and shall be exercisable for cash only with expected total proceeds to us, if exercised, equal to approximately \$6.0 million. The warrants were valued at their fair value on the date of issuance and we incurred a non-cash charge equal to \$4.0 million in connection with the issuance. The existing secured revolving credit facility of \$8.5 million with PharmaBio remains available with the original maturity date of December 10, 2004 being extended until December 31, 2006. See “Liquidity and Capital Resources.”

Laboratorios del Dr. Esteve, S.A.

In 1999, we entered into a corporate partnership with Laboratorios del Dr. Esteve, S.A. (Esteve), to develop, market and sell Surfaxin, primarily in southern Europe. In 2002, we significantly expanded our relationship with Esteve by entering into a new collaboration arrangement, which superseded the 1999 agreement, and expanded the territory covered by those original agreements to all of Europe, Central and South America, and Mexico. Esteve was obligated to provide certain commercialization services for Surfaxin for the prevention of RDS in premature infants, the treatment of MAS in full-term infants and the treatment of ARDS in adult patients. Our exclusive supply agreement with Esteve provided that Esteve would purchase all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for ARDS and make certain milestone payments to us upon the attainment of European marketing regulatory approval for Surfaxin. In connection with the 2002 expanded agreement, Esteve purchased 821,862 shares of common stock at \$4.867 per share for \$4.0 million in gross proceeds and paid a non-refundable licensing fee of \$500,000. We have accounted for the license fees and reimbursement of research and development expenditures associated with the Esteve collaboration as deferred revenue.

In December 2004, we reached an agreement with Esteve to restructure our corporate partnership for the development, marketing and sales of our products in Europe and Latin America. This restructured partnership supersedes the existing sublicense and supply agreements we had entered into with Esteve in March 2002. Under the revised partnership, we regained full commercialization rights in key European markets, Central America and South America for SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults. Esteve will focus on Andorra, Greece, Italy, Portugal, and Spain, and now has development and marketing rights to a broader portfolio of potential SRT products. Under the restructured collaboration, Esteve will pay us a transfer price on sales of Surfaxin and other SRT that is increased from that provided for in the previous collaborative arrangement. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the revised territory. Esteve has agreed to make stipulated cash payments to us upon its achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

In consideration for regaining commercial rights in the 2004 restructured partnership, we issued to Esteve 500,000 shares of common stock for no cash consideration, valued at \$3.5 million. We incurred a non-cash charge, including the value of the shares issued and other costs related to the restructuring, of \$4.1 million. We also granted to Esteve rights to additional potential SRT products in our pipeline, and also agreed to pay to Esteve 10% of cash up-front and milestone fees that we may receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain other SRTs in the territory for which we had previously granted a license to Esteve. Payments to Esteve in respect of any such up-front and milestone fees are not to exceed \$20 million in the aggregate.

Plan of Operations

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued implementation of a long-term business strategy focused on becoming a fully integrated biotechnology company in order to develop and commercialize the potential of our SRT pipeline.

We anticipate that during the next 12 to 24 months we will:

- (i) increase research, development and regulatory activities in an effort to develop a broad pipeline of potential SRT for respiratory diseases. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the following risks discussed in "Risks Related to Our Business" - "Our technology platform is based solely on our proprietary, precision-engineered surfactant technology. Ongoing clinical trials for our lead surfactant replacement therapies may be delayed, or fail, which will harm our business;" - "The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain."

Our major research and development projects include:

SRT for Neonatal Intensive Care Unit

In order to address the most prevalent respiratory disorders affecting infants in the NICU, we are conducting several NICU therapeutic programs targeting respiratory conditions cited as some of the most significant unmet medical needs for the neonatal community.

We have received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants, and have filed an MAA with the EMEA for clearance to market Surfaxin in Europe. We anticipate potential approval and commercial launch of Surfaxin in the United States and potential EMEA approval to occur in the second quarter of 2006. Activities associated with our regulatory filings with the FDA and EMEA are ongoing.

Presently, we are conducting a Phase 2 clinical trial for Surfaxin for the treatment of Chronic Lung Disease (CLD, also known as Bronchopulmonary Dysplasia) in premature infants. The Phase 2 clinical trial for Surfaxin for the treatment of CLD is a double-blind, controlled trial that will enroll up to 210 very low birth weight premature infants born at risk for developing CLD to determine the safety and tolerability of administering up to 5 total doses of Surfaxin in the first 10 days of life as a therapeutic approach for the prevention of CLD. This study is designed to determine whether such treatment can decrease the proportion of infants on mechanical ventilation or oxygen or the incidence of death or CLD. In October, the Office of Orphan Products Development of the FDA granted orphan drug designation to Surfaxin, for the treatment of CLD in premature infants. We have recently modified the study protocol and now anticipate the results of this trial to be available in the third quarter of 2006.

Aerosurf™ is our precision-engineered aerosolized SRT administered via nCPAP intended to treat premature infants at risk for respiratory failures. We recently completed and announced the results of our first pilot Phase 2 clinical study of Aerosurf, which was designed as an open label, multicenter study to evaluate the feasibility, safety and tolerability of Aerosurf delivered via nCPAP for the prevention of RDS in premature infants administered within 30 minutes of birth over a three hour duration. The study showed that it is feasible to deliver Aerosurf via nCPAP and the treatment was generally safe and well tolerated. We are currently in the process of evaluating a collaborative partnership to secure a specific aerosol generation technology and engineering solution which we believe may enhance the delivery of Aerosurf. If we can successfully secure such collaboration, we anticipate being in a position to initiate additional Phase 2 studies of an aerosol generation technology in 2006.

We have discontinued our Phase 2 clinical trial of our proprietary Surfaxin lavage for use as a prophylactic or early treatment for patients who are at risk of developing MAS.

SRT for Critical Care and Hospital Indications

We are presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of our SRT for the treatment of adults with ARDS. In December 2004, we announced what we believe to be encouraging preliminary data from this trial and that we were modifying the trial protocol to allow for increased enrollment of up to 160 patients. Patients will be randomized to either receive our SRT or the current standard of care, which is mechanical ventilation and support therapies. The primary endpoint of this trial is the incidence rate of patients being alive and off mechanical ventilation at Day 28. Key secondary endpoints include mortality at the end of Day 28 and safety and tolerability of our SRT and the bronchoscopic lavage procedure. Results of the Phase 2 trial are anticipated to be available in the first quarter of 2006.

We are also evaluating the development of aerosol formulations of SRT to potentially address ALI, asthma, COPD, and other respiratory conditions. In 2004, we completed a successful Phase 1b clinical trial intended to evaluate the tolerability and lung deposition of our precision-engineered SRT, delivered as an inhaled aerosol to treat patients with mild-persistent asthma (development name DSC-104). We are currently in the process of evaluating aerosol generation technologies which will be necessary for the development of SRT products to address these respiratory conditions. Given the current focus on developing the SRT pipeline for the NICU, we will be assessing the development priority of these programs in 2006.

- (ii) invest in and support a long-term manufacturing strategy for the production of our precision-engineered surfactant drug product including: (a) certain measures required for our current contract manufacturer, Laureate, to be in compliance with cGMPs to support the FDA's review of and potential approval of our NDA for Surfaxin for the prevention of RDS in premature infants; (b) further development and scale-up of the Laureate facility; (c) securing additional manufacturing capabilities to meet production needs as they expand, including alternative contract manufacturers and acquiring our own manufacturing facility. We anticipate that our manufacturing capabilities through Laureate should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the prevention of RDS in premature infants and all of our anticipated clinical-scale production requirements including Surfaxin for the treatment of ARDS in adults. See "Risks Related to Our Business" - "In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product which may not be readily available" and "If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products;"

We intend to use the \$17.0 million proceeds from our draw-down on the CEFF in September 2005 to acquire a dedicated manufacturing operation as a strategic investment for the manufacture of Surfaxin and the development of our SRT pipeline or for general corporate purposes.

- (iii) build our own specialty pulmonary United States sales and marketing organization to execute the commercial launch of Surfaxin, if approved, in the United States. Our sales and marketing force will initially focus on opportunities in the NICU and, as products are developed, to expand to critical care and hospital settings. This strategic initiative, led by the anticipated commercial launch of Surfaxin, is intended to allow us to fully control our own sales and marketing operation, establish a strong presence in the NICU and optimize company economics;
- (iv) secure, through a corporate partnership, and develop aerosol generating technology and engineering capabilities for our aerosol SRT pipeline programs, including AerosurfTM;
- (v) implement our commercialization strategy for Surfaxin in Europe and the rest of the world through corporate partnerships; and
- (vi) invest in additional general and administrative resources primarily to support our intellectual property portfolios, including building and enforcing our patent and trademark positions, our business development initiatives, financial systems and controls and management information technologies.

We will need to generate significant revenues from product sales and or related royalties and transfer prices to achieve and maintain profitability. Through September 30, 2005, we had no revenues from any product sales, and had not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. In addition, our results are dependent upon the performance of our strategic partners and third party contract manufacturers and suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through December 31, 2004, we had not generated taxable income. On December 31, 2004, net operating losses available to offset future taxable income for Federal tax purposes were approximately \$140.7 million. The future utilization of such loss carryforwards may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we have a research and development tax credit carryforward of \$2.6 million at December 31, 2004. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 and continuing through 2023.

Results of Operations

The net loss for the three and nine month periods ended September 30, 2005 were \$10.4 million (or \$0.19 per share) and \$29.5 million (or \$0.56 per share), respectively. The net loss for the three and nine month periods ended September 30, 2004 were \$8.4 million (or \$0.18 per share) and \$26.2 million (or \$0.57 per share), respectively.

Revenue

Revenue for the three and nine months ended September 30, 2005 was \$20,000 and \$105,000, respectively. Revenue for the three and nine months ended September 30, 2004 was \$236,000 and \$1,075,000, respectively. This revenue is primarily associated with our corporate partnership agreement with Esteve to develop, market and sell Surfaxin in Southern Europe, as was in effect during such periods, whereby Esteve funded a portion of the RDS clinical trial costs and had committed to fund up to \$6 million of ARDS development costs. The decrease in revenue is due to the restructuring of our corporate partnership with Esteve in December 2004 (primarily as it relates to ARDS development costs) and the extension of the amortization period (based on the anticipated approval timeline for certain world health regulatory authorities) for revenue recognition of the funding previously provided to us in connection with RDS clinical trial costs.

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2005 were \$5.7 million and \$16.7 million, respectively, and for the three and nine months ended September 30, 2004 were \$5.7 million and \$18.8 million, respectively. Research and development costs consist primarily of expenses associated with research and pre-clinical operations, manufacturing development, clinical and regulatory operations and other direct clinical trial activities.

The change in research and development expenses for the three and nine months ended September 30, 2005 compared to the same periods for 2004 primarily reflect:

- (i) manufacturing activities, including manufacturing personnel costs to support further development and preparation for Surfaxin commercial process activities of our current contract manufacturer, Laureate, and securing additional manufacturing capabilities to meet production needs as they expand, including alternative contract manufacturers and acquiring our own manufacturing facility. Expenses related to manufacturing activities were \$3.0 million and \$7.0 million for the three and nine months ended September 30, 2005, respectively. Expenses related to manufacturing activities were \$1.1 million and \$4.6 million for the three and nine months ended September 30, 2004, respectively. Included in manufacturing activities for the three and nine months ended September 30, 2005 were primarily costs associated with the implementation of enhancements to quality controls, process assurances and documentation requirements that support the clinical and commercial production process at our contract manufacturer, Laureate Pharma, Inc., in response to the FDA's Form-483 inspectional observations. Included in manufacturing activities for the three and nine months ended September 30, 2004 were expenses associated with the transfer (completed in 2004) and ongoing validation activities related to our manufacturing equipment and processes at Laureate to support the production of clinical and commercial drug supply of Surfaxin in conformance with cGMPs; and
- (ii) research and development expenses, excluding manufacturing activities, were \$2.7 million and \$9.7 million for the three and nine months ended September 30, 2005, respectively, compared to \$4.6 million and \$14.1 million for the three and nine months ended September 30, 2004, respectively. The change is primarily due to costs in 2004 associated with clinical and regulatory activities for Surfaxin for RDS, principally the NDA filing, a related milestone payment for the license of Surfaxin, and follow-up clinical activity for the related two Phase 3 clinical trials. For the three and nine months ended September 30, 2005, research and development activities primarily reflect regulatory activities associated with Surfaxin for RDS (specifically the U.S. FDA Approvable Letter and the Marketing Authorization Application with the EMEA) and clinical activities related to the Phase 2 clinical trials for ARDS in adults, CLD in premature infants and Aerosurf for Neonatal Respiratory Failures.

General and Administrative Expenses

General and administrative expenses for the three and nine months ended September 30, 2005 were \$4.8 million and \$13.2 million, respectively, and for the three and nine months ended September 30, 2004, were \$2.9 million and \$8.4 million, respectively. These costs consist primarily of executive management, finance and accounting, business and commercial development, pre-launch commercial sales and marketing, legal, facility and other administrative costs.

The increase in general and administrative expenses for the three and nine months ended September 30, 2005 compared to the same periods for 2004 primarily reflects:

- (i) pre-launch sales, marketing and medical affairs activities related to building our own specialty United States commercial organization to focus initially on the commercial and medical promise of our SRT to address respiratory conditions in the NICU, if approved. Expenses for pre-launch commercialization activities primarily include management and operational staffing, medical science liaisons, market research, development of promotional materials, advisory boards, publication planning, and representation at industry conferences. Expenses for the three and nine months ended September 30, 2005 were \$2.7 million and \$7.2 million, respectively, compared to \$1.3 million and \$3.3 million, respectively, for the same periods last year; and
- (ii) general and administrative expenses, excluding pre-launch commercialization activities, were \$2.1 million and \$6.0 million for the three and nine months ended September 30, 2005, respectively, compared to \$1.6 million and \$5.0, respectively, for the same periods last year. These expenditures include financial and information technology capabilities, business development activities related to potential strategic collaborations, legal activities related to the preparation and filing of patents in connection with the expansion of our SRT pipeline, facilities expansion activities to accommodate existing and future growth, and corporate governance initiatives to comply with the Sarbanes-Oxley Act.

Other Income / (Expense)

Other income/(expense) for the three and nine months ended September 30, 2005 was \$67,000 and \$189,000, respectively, compared to (\$37,000) and (\$106,000), for the three and nine months ended September 30, 2004, respectively.

Interest income for the three and nine months ended September 30, 2005 was \$328,000 and \$884,000, respectively, compared to \$125,000 and \$277,000, for the three and nine months ended September 30, 2004, respectively. The increase is primarily due to higher average cash balances and a general increase in earned market interest rates.

Interest expense for the three and nine months ended September 30, 2005 was (\$261,000) and (\$695,000), respectively, compared to (\$162,000) and (\$383,000), for the three and nine months ended September 30, 2004, respectively. The increase is primarily due to interest expense associated with our credit facility and capital lease financing arrangements. See "Liquidity and Capital Resources."

Liquidity and Capital Resources

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2005, we had cash, cash equivalents, restricted cash and marketable securities of \$50.3 million as compared to \$32.7 million as of December 31, 2004. The change from December 31, 2004 is primarily due to: (i) net proceeds of \$27.4 million from a registered direct public offering of 5,060,000 shares of our common stock; (ii) proceeds of \$17.0 million pursuant to the CEFF through the issuance of 3,012,055 shares of our common stock; (iii) cash used in operating and investing activities of \$30.4 million; (iv) \$2.7 million accessed under our secured credit facility from PharmaBio and capital lease facility with GECC; and (v) \$0.9 million received from the exercise of stock options.

Additionally, on November 2, 2005, we sold 650,000 shares of our common stock to Esteve for aggregate proceeds of approximately \$4.5 million.

Committed Equity Financing Facility (CEFF)

We have a CEFF with Kingsbridge, pursuant to which Kingsbridge is committed to finance up to \$75.0 million of capital to support our future growth, which expires in October 2007. Subject to certain conditions and limitations, from time to time under the CEFF, we may require Kingsbridge to purchase newly-issued shares of its common stock at a discount between 6% and 10% of the volume weighted average price of our common stock and thus raise capital as required, at the time, price and in amounts deemed suitable to us. In September 2005, we entered into a financing pursuant to the CEFF resulting in proceeds of \$17.0 million from the issuance of 3,012,055 shares of common stock at an average price of \$5.64 (the NASDAQ volume weighted average sales price of our common stock of \$6.27 per share less the applicable discount rate provided for by the CEFF). We intend to use these proceeds to acquire a dedicated manufacturing operation as a strategic investment for the manufacture of Surfaxin, the development of our SRT pipeline, and for general corporate purposes. Subject to the terms and conditions of the CEFF, \$50.8 million remains available as of September 30, 2005. We anticipate using additional portions of the available CEFF over the remainder of 2005 to support manufacturing, development and commercialization activities associated with the potential commercial launch of Surfaxin in the second quarter of 2006.

Secured, Revolving Credit Facility and Capital Lease Arrangement

Secured Credit Facility with Quintiles

We have an \$8.5 million secured credit facility with PharmaBio, Quintiles' strategic investment group affiliate. Interest is paid quarterly in arrears at a rate of approximately 8.75%. During the first quarter of 2005, we accessed the remaining \$2.6 million available under the credit facility and currently the entire \$8.5 million is outstanding and due in December 2006.

Capital Lease Financing Arrangement with GECC

We have a capital lease financing arrangement with the Life Science and Technology Finance Division of GECC. Under this arrangement, we purchase capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finance those purchases through this capital lease financing arrangement. This arrangement provides us with financing for up to \$9.0 million, of which \$1.5 million is contingent upon FDA approval of Surfaxin for the prevention of RDS in premature infants. The funds are available to us through April 2006. Laboratory and manufacturing equipment is leased over 48 months with an interest rate equal to 9.39% per annum and all other equipment is leased over 36 months with an interest rate equal to 9.63% per annum. For the three and nine months ended September 30, 2005, we used \$325,000 and \$757,000 under the capital lease financing arrangement. As of September 30, 2005, we had used \$3.8 million of the financing available under the line of credit and, after giving effect to principal payments, \$2.6 million was outstanding. As of September 30, 2005, \$3.7 million was available under the capital lease financing arrangement.

Lease Agreements

We maintain facility leases for our operations in Pennsylvania and California.

We maintain our headquarters in Warrington, Pennsylvania. The facility is 39,594 square feet and serves as the main operating facility for clinical development, regulatory, sales and marketing and administration. The lease expires in February 2010 with total aggregate payments of \$4.6 million.

We also lease 11,000 square feet of office and laboratory space in Doylestown, Pennsylvania. We maintain the Doylestown facility for the continuation of analytical laboratory activities under a lease that expires in February 2006, subject to a 6-month extension.

We lease office and laboratory space in Mountain View, California. The facility is 16,800 square feet and houses our aerosol development operations. The lease expires in June 2008 with total aggregate payments of \$804,000.

Working Capital

We believe our current working capital is sufficient to meet planned activities into 2006, before taking into account any amounts that may be available through the use of the CEFF. We anticipate using additional portions of the available CEFF over the remainder of 2005 to support manufacturing, development and commercialization activities associated with the potential commercial launch of Surfaxin in the second quarter of 2006.

We will need additional financing from investors or collaborators to complete research and development, manufacturing, and commercialization of our current product candidates under development. Working capital requirements will depend upon numerous factors, including, without limitation, the progress of research and development programs, clinical trials, timing and cost of obtaining regulatory approvals, timing and cost of sales and marketing activities, levels of resources that we devote to the development of manufacturing and marketing capabilities, technological advances, status of competitors, ability to establish collaborative arrangements with other organizations, the ability to defend and enforce intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

On October 11, 2005 we filed a universal shelf registration statement with the SEC for the proposed offering from time to time of up to \$100 million of our debt or equity securities. The universal shelf registration statement was declared effective by the SEC on October 24, 2005. Presently, we have not issued any securities pursuant to this universal shelf registration statement.

We filed a shelf registration statement on Form S-3 with the SEC on December 19, 2003 for the proposed offering from time to time of up to 6.5 million shares of our common stock. On February 17, 2005, we filed a registration statement on Form S-3MEF to register an additional 1,468,592 shares of common stock for issuance in connection with the December 2003 shelf registration statement. We have made a number of issuances pursuant to these registration statements (see below) and currently there remain 58,592 shares reserved for potential future issuance under the February 2005 registration statement.

Historically, our working capital has been provided from the proceeds of public and private financings and strategic alliances:

- On November 2, 2005, we sold 650,000 shares of our common stock to Esteve, at a price per share of \$6.88, for aggregate proceeds of approximately \$4.5 million. The shares were issued pursuant to a registration statement on Form S-3MEF filed with the SEC on February 17, 2005.
- In September 2005, we entered into a financing pursuant to the CEFF resulting in proceeds of \$17.0 million from the issuance of 3,012,055 shares at an average price of \$5.64 (the NASDAQ volume weighted average sales price of our common stock of \$6.27 per share less the applicable discount rate provided for by the CEFF),

- In February 2005, we completed a registered direct public offering of 5,060,000 shares of common stock at \$5.75 per share, resulting in gross proceeds of \$29.1 million. The shares were issued pursuant to the shelf registration statement filed in December 2003 and the additional registration statement filed in February 2005.
- In December 2004, we entered into a financing pursuant to the CEFF resulting in proceeds of \$7.2 million from the issuance of 901,742 shares at an average price of \$7.98 (the NASDAQ volume weighted average sales price of our common stock of \$8.84 per share less the applicable discount rate provided for by the CEFF).
- In April 2004, we completed an underwritten public offering of 2.2 million shares of common stock priced at \$11.00 per share resulting in gross and net proceeds of \$24.2 million and \$22.8 million, respectively. The shares were issued pursuant to the shelf registration statement filed in December 2003.

We will require substantial additional funding to conduct our business, including our expanded research and product development activities and establishment of commercialization resources. Based on our current operating plan, we believe that our currently available resources, before taking into account any amounts that may be available under our CEFF with Kingsbridge and our capital lease financing arrangement with GECC, will be adequate to satisfy our capital needs into 2006. Our future capital requirements will depend on the results of our manufacturing activities, research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative ventures with potential corporate partners.

We may, in some cases, elect to develop products on our own instead of entering into collaboration arrangements and this would increase our cash requirements. Other than our credit facility with PharmaBio, our CEFF with Kingsbridge and our capital lease financing arrangement with GECC, we have not entered into any additional arrangements to obtain additional financing. The sale of additional equity and debt securities may result in additional dilution to our shareholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to them, if at all. If we fail to enter into collaborative ventures or to receive additional funding, we may have to reduce significantly the scope of or discontinue our planned research, development and commercialization activities, which could significantly harm our financial condition and operating results. Furthermore, we could cease to qualify for listing of common stock on the NASDAQ National Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See “Risks Related to Our Business” - “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;” - “The market price of our stock may be adversely affected by market volatility;” and “ - A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital.”

Risks Related to Our Business

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.

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

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

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of September 30, 2005, we have an accumulated deficit of approximately \$172.6 million and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

Our technology platform is based solely on our proprietary precision-engineered, surfactant technology. Our ongoing clinical trials for our lead surfactant replacement technologies may be delayed, or fail, which will harm our business.

Our precision-engineered surfactant platform technology is based on the scientific rationale of SRT to treat life threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this platform technology. We have received an Approvable Letter from the FDA for Surfaxin, our lead product, for the prevention of RDS in premature infants, and have filed an MAA with the EMEA for clearance to market Surfaxin in Europe. The Approvable Letter from the FDA contains conditions that we must meet in order to obtain approval and they primarily involve finalizing labeling and correcting previously reported manufacturing issues. We submitted a Response Letter to the FDA's Approvable Letter on July 29, 2005. We have received formal written notification from the FDA, following its review of our Response Letter, outlining select items that need to be further addressed in order for the FDA to deem the response complete. Our previously submitted responses to the Approvable Letter have been accepted by the FDA as a complete response as of October 5, 2005. This date also marks the start of the FDA's six month target to complete its review of our NDA for Surfaxin for the prevention of RDS in premature infants. We believe that the quality systems and documentation control enhancements that we have implemented jointly with Laureate to support our response to the FDA prepare us for the FDA's reinspection of Laureate's Totowa facility within the six month review cycle. Some pre-approval activities related to our Surfaxin manufacturing process, including process validation, have been completed, while other reinspection activities are ongoing. Assuming the adequacy of such corrective actions, the approval of Surfaxin is now anticipated in April 2006 with potential commercial launch to occur in the second quarter of 2006. Currently, we are conducting a Phase 2 clinical trial for the treatment of ARDS in adults and we have initiated a Phase 2 clinical trial using Aerosurf to potentially treat premature infants in the NICU suffering from Neonatal Respiratory Failures and a Phase 2 clinical trial using Surfaxin for the prevention of CLD. See also "Overview" above, especially paragraph (i) in the description of our business strategy, and "Plan of Operations".

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

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

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

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

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of our products. Presently, Laureate is our sole clinical manufacturing facility that has been qualified to produce appropriate clinical grade material of our drug product for use in our ongoing clinical studies. In January 2005, the FDA issued an inspection report (FDA Form-483) to Laureate citing certain observations concerning Laureate's compliance with cGMPs in connection with the FDA's review of our New Drug Application (NDA) for Surfaxin for the prevention of RDS in premature infants. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. Certain quality systems and documentation control enhancements have been implemented by us and Laureate in response to the FDA's inspection report. See "Overview" above, especially paragraph (i) in the description of our business strategy, and "Plan of Operations".

We anticipate that our manufacturing capabilities through Laureate, upon successful completion and implementation of our remedial activities, should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the prevention of RDS in premature infants and our other SRT programs for our planned clinical trials. If the FDA does not accept the cGMP Action Plan, or if we or Laureate do not adequately address the initiatives set forth therein, the FDA may delay its approval of our NDA for Surfaxin or reject our NDA. Any delay in the approval of the NDA, or the rejection thereof, will have a material adverse effect on our business.

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

We may in the future elect to manufacture some of our products on our own. We currently own certain specialized manufacturing equipment, employ certain manufacturing managerial personnel, and we are considering an investment in additional manufacturing equipment; however, we do not presently maintain a complete manufacturing facility. Currently, we are in the process of evaluating a potential transaction to acquire a dedicated manufacturing operation as a strategic investment for the manufacture of Surfaxin and the development of our SRT pipeline although there can be no assurances that any such transaction will occur. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

The FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs or similar requirements that the FDA or corresponding foreign regulators establish. Contract manufacturers may face manufacturing or quality control problems causing product production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's cGMP requirements, or those of comparable foreign regulatory authorities, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products. See also "Risks Related to Our Business - In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product, which may not be readily available."

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

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We rely on third party contract manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical trials of our products. Laureate, our contract manufacturer, may not be able to produce Surfaxin to appropriate standards for use in clinical studies. Manufacturing or quality control problems have already and may again occur at Laureate or our other contract manufacturers, causing production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's cGMP requirements necessary to continue manufacturing our ingredients or drug product. If any such suppliers or manufacturers of our products fail to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products. See also "Risks Related to Our Business - If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products."

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

We will need substantial additional funding to conduct our presently planned research and product development activities. Based on our current operating plan, we believe that our currently available financial resources will be adequate to satisfy our capital needs into 2006. Our future capital requirements will depend on a number of factors that are uncertain, including the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process, among others. We will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may also continue to seek additional funding through capital lease transactions. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

We have not entered into arrangements to obtain any additional financing, except for the CEFF with Kingsbridge, our revolving credit facility with PharmaBio and our capital equipment lease financing arrangement with GECC. Any additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations. See "Risks Related to Our Business - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders."

Furthermore, we could cease to qualify for listing of our securities on the NASDAQ National Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See “Risks Related to Our Business - The market price of our stock may be adversely affected by market volatility.”

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

There are 11,461,203 shares of our common stock that are reserved for issuance under the CEFF arrangement with Kingsbridge, 375,000 of which are issuable under the warrant we granted to Kingsbridge. The issuance of shares of our common stock under the CEFF and upon exercise of the warrant will have a dilutive impact on our other stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. In addition, if we access the CEFF, we will issue shares of our common stock to Kingsbridge at a discount of between 6% and 10% of the daily volume weighted average price of our common stock during a specified period of trading days after we access the CEFF. Issuing shares at a discount will further dilute the interests of other stockholders. In September 2005, \$17.0 million was successfully raised under the CEFF over a 15 day period. We anticipate using additional portions of the available CEFF over the remainder of 2005 to support manufacturing, development and commercialization activities associated with the potential commercial launch of Surfaxin in the second quarter of 2006.

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

We may not be able to meet the conditions we are required to meet under CEFF and we may not be able to access any portion of the remaining \$50.8 million available under the CEFF. In addition, we are dependent upon the financial ability of Kingsbridge to fund the CEFF. Any failure by Kingsbridge to perform its obligations under the CEFF could have a material adverse effect upon us.

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

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

On April 13, 2004, we filed an NDA for Surfaxin for the prevention of RDS in premature infants. The FDA accepted the NDA filing and in February 2005 we received an Approvable Letter from the FDA with respect to our NDA. The Approvable Letter contains conditions that we must meet prior to obtaining final U.S. marketing approval for Surfaxin. Our previously submitted responses to the Approvable Letter have been accepted by the FDA as a complete response as of October 5, 2005. The conditions that we must meet primarily involve finalizing labeling and correcting previously reported manufacturing issues, however, the FDA might still reject the NDA. See also “Overview” above, especially paragraph (i) in the description of our business strategy, and “Plan of Operations”.

We have also submitted an MAA with the EMEA for clearance to market Surfaxin for the prevention and treatment of RDS in premature infants. The EMEA has validated the MAA indicating that the application is complete and that the review process has begun. However, the EMEA may not complete the review or may reject the MAA.

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

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

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least the first quarter of 2006, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for our precision-engineered surfactant-based therapy, MAS in full-term 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. The FDA has also granted us Orphan Drug Designation for three of our intended indications for Surfaxin: ARDS in adults; RDS in infants; and MAS in full-term infants. To support our development of Surfaxin for the treatment of MAS, the FDA has awarded us an Orphan Products Development Grant. Fast-Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast-Track Status provisions are designed to expedite the FDA’s review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years.

The EMEA has granted Orphan Medicinal Product designation for three of our intended indications for Surfaxin: RDS in premature infants, MAS in full-term infants and ALI in adults.

Our products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

The FDA and comparable foreign agencies could withdraw any approvals we obtain, if any. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve our products, we will not be able to market our products.

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

Our strategy for the completion of the required development and clinical testing of our products and for the manufacturing, marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. We have a revised collaboration arrangement with Esteve for Surfaxin and certain other of our product candidates that is now focused on key Southern European markets. Within these countries, Esteve will be responsible for the development and marketing of Surfaxin for a broader portfolio of indications, including the prevention/treatment of RDS in premature infants, MAS in full-term infants and ALI/ARDS in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining EMEA approval for commercialization of Surfaxin in Europe for several indications. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to EMEA filings.

If we or Esteve breach or terminate the agreements that make up such collaboration arrangements or Esteve otherwise fails to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin which Esteve. Accordingly, we may need to enter into additional collaboration agreements and our success, particularly outside of the United States, may depend upon obtaining additional collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed products. We are currently in the process of evaluating aerosol generation technologies which will be necessary for the development of SRT products to address certain respiratory conditions and the failure to find a collaborative partner for such development may have a material adverse effect on our business.

We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See "Risks Related to Our Business - We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates."

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

We seek patent protection for our drug candidates so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

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

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

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

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

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson and its wholly owned subsidiary, Ortho Pharmaceutical Corporation, which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risks Related to Our Business - If we cannot meet requirements under our license agreements, we could lose the rights to our products."

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

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

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

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

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

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

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

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

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

We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates.

If we successfully develop and obtain regulatory approval for Surfaxin and the other product candidates that we are currently developing, we may: (1) market and sell them through our sales force, (2) license some of them to large pharmaceutical companies and/or (3) market and sell them through other arrangements, including co-promotion arrangements.

We currently have a limited sales and marketing team and we plan to further develop our marketing and sales team as we expect to rely primarily on such team to market Surfaxin in the United States, if Surfaxin is approved by the FDA. Recruiting, training and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is 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. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates.

Developing a marketing and sales team to market and sell products is a difficult, significantly expensive and time-consuming process. We have no prior experience developing a marketing and sales team and may be unsuccessful in our attempt to do so. If we are unable to develop an internal sales and marketing operation, we may not be able to increase market awareness and sell our products.

Establishing the expertise necessary to successfully market and sell Surfaxin, or any other product, will require a substantial capital investment. 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, the performance of third party collaborators with whom we may contract. Accordingly, we may not have sufficient funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

We may also 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.

We may also rely on third-party distributors to distribute our products or enter into marketing alliances to sell our products. We may not be successful in entering into distribution arrangements and marketing alliances with third parties. Our failure to successfully develop a marketing and sales team or to 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. 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 also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties in a timely manner or if they fail to perform, it could adversely affect sales of our products. We and any of our third-party collaborators must also market our products in compliance with federal, state and local laws relating to the providing of incentives and inducements. Violation of these laws can result in substantial penalties. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, or if our distributors fail to promote our products, we will have difficulty maintaining and increasing the sales of our products.

We may be unable to either establish marketing and sales capabilities or enter into corporate collaborations necessary to successfully commercialize Surfaxin or our other potential products.

We have limited experience in marketing or selling pharmaceutical products and have limited marketing and sales resources. To achieve commercial success for Surfaxin, or any other approved product, we must either rely upon our limited marketing and sales force and related infrastructure, or enter into arrangements with others to market and sell our products. We intend to promote Surfaxin in the United States through our own dedicated marketing and sales team. Recruiting, training and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is intense, and we may not be able to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin.

In addition, establishing the expertise necessary to successfully market and sell Surfaxin, or any other product, will require a substantial capital investment. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, as described above, partnering of clinical programs at opportune times and continued prudent fiscal management. Accordingly, we may not have the funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

Moreover, Surfaxin competes, and our product candidates in development are likely to compete, with products of other companies that currently have extensive and well-funded marketing and sales operations. Because these companies are capable of devoting significantly greater resources to their marketing and sales efforts, our marketing and sales efforts may not compete successfully against the efforts of these other companies.

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

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

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have employment agreements with seven officers expiring in December 2006. Each employment agreement provides that its term shall automatically be extended for one additional year, unless at least 90 days prior to January 1 either party gives notice that it does not wish to extend the agreement. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

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

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

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

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

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

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

Presently, there are no approved drugs that are specifically indicated for the prevention and treatment of MAS in full-term infants or ALI/ARDS in adults. Current therapy consists of general supportive care and mechanical ventilation.

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

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that therapeutic developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

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

The clinical testing of, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to \$10.0 million per occurrence and \$10.0 million in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock.

We expect to face uncertainty over reimbursement and healthcare reform.

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

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

As of September 30, 2005, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 14% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

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

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

Our common stock is listed for quotation on the NASDAQ National Market. During the nine month period ended September 30, 2005, the price of our common stock has ranged from \$5.05 to \$9.15. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the nine-month period ended September 30, 2005, the average daily trading volume in our common stock was approximately 587,000 shares and the average number of transactions per day was approximately 1,804. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

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

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

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

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of September 30, 2005, we had 56,791,243 shares of common stock issued and outstanding.

We have an effective universal shelf registration statement on Form S-3, 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. In addition, 58,592 shares of our common stock remain available for sale under our registration statement on Form S-3MEF, filed with the SEC on February 17, 2005. We have no immediate plans to sell any securities under these registration statements. However, we may issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

Additionally, there are 11,086,203 shares of our common stock that are currently reserved for issuance under the CEFF. See “Risks Related to Our Business - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.”

As of September 30, 2005, up to 10,665,343 shares of our common stock were issuable upon exercise of outstanding options and warrants. Holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our common stock.

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

Provisions of our Restated Certificate of Incorporation, as amended, our Shareholders Rights Agreement and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Restated Certificate of Incorporation, as amended, allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock. We have adopted a shareholders rights agreement which under certain circumstances would significantly impair the ability of third parties to acquire control of us without prior approval of our Board of Directors thereby discouraging unsolicited takeover proposals. The rights issued under the shareholders rights agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is confined to our cash, cash equivalents and available for sale securities. We place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer. We currently do not hedge interest rate or currency exchange exposure. We classify highly liquid investments purchased with a maturity of three months or less as “cash equivalents” and commercial paper and fixed income mutual funds as “available for sale securities.” Fixed income securities may have their fair market value adversely affected due to a rise in interest rates and we may suffer losses in principal if forced to sell securities that have declined in market value due to a change in interest rates.

Item 4. Controls and Procedures

(a) Evaluation of disclosure controls and procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that as of the end of the period covered by this report, the disclosure controls and procedures were effective in their design to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

(b) Changes in internal controls

There were no changes in internal controls over financial reporting or other factors that could materially affect those controls subsequent to the date of our evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

In September 2005, we entered into a financing pursuant to the CEFF resulting in proceeds of \$17.0 million from the issuance of 3,012,055 shares of common stock at an average price of \$5.64 (the NASDAQ volume weighted average sales price of our common stock of \$6.27 per share less the applicable discount rate provided for by the CEFF). As of September 30, 2005, \$50.8 million remains available under the CEFF.

In the quarter ended September 30, 2005, pursuant to the exercise of outstanding stock options and warrants, we issued an aggregate of 88,036 shares of common stock at various exercise prices ranging from \$1.46 to \$7.46 per share for an aggregate consideration equal to \$398,747. We relied on the exemption from registration provided by Section 4(2) of the Securities Act for these transactions. No broker-dealers were involved in the sale and no commissions were paid.

We have a voluntary 401(k) savings plan covering eligible employees. Effective January 1, 2003, we allowed for periodic discretionary matches of newly issued shares of common stock with the amount of any such match determined as a percentage of each participant's cash contribution. The total fair market value of our match of common stock to the 401(k) for the quarter ended September 30, 2005 was \$54,143.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibits are listed on the Index to Exhibits at the end of this Quarterly Report. The exhibits required by Item 601 of Regulation S-K, listed on such Index in response to this Item, are incorporated herein by reference.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**DISCOVERY LABORATORIES, INC.
(Registrant)**

Date: November 9, 2005

By: /s/ Robert J. Capetola

Robert J. Capetola, Ph.D.
President and Chief Executive Officer

Date: November 9, 2005

By: /s/ John G. Cooper

John G. Cooper
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

INDEX TO EXHIBITS

The following exhibits are included with this Quarterly Report. All management contracts or compensatory plans or arrangements, if any, are marked with an asterisk.

| <u>Exhibit No.</u> | <u>Description</u> | <u>Method of Filing</u> |
|--------------------|--|-------------------------|
| 31.1 | Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) of the Exchange Act. | Filed herewith. |
| 31.2 | Certification of Chief Financial Officer and Principal Accounting Officer Pursuant to Rule 13a-14(a) of the Exchange Act. | Filed herewith. |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | Filed herewith. |

CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Robert J. Capetola, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Discovery Laboratories, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
 - d) disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2005

By: /s/ Robert J. Capetola

Robert J. Capetola, Ph.D.
President and Chief Executive Officer

CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, John G. Cooper, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Discovery Laboratories, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
 - d) disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2005

By: /s/ John G. Cooper

John G. Cooper
Executive Vice President and Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Discovery Laboratories, Inc. (the "Company"), for the period ended September 30, 2005, as filed with the Securities and Exchange Commission (the "Commission") on the date hereof (the "Report"), each of the undersigned, in his capacity as an officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Commission or its staff upon request.

Date: November 9, 2005

By: /s/ Robert J. Capetola

Robert J. Capetola, Ph.D.
President and Chief Executive Officer

Date: November 9, 2005

By: /s/ John G. Cooper

John G. Cooper
Executive Vice President and Chief Financial Officer
