DISCOVERY LABORATORIES INC /DE/
Form 10-Q
May 10, 2006

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

FORM 10-Q

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

For the quarterly period ended March 31, 2006

or

o **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	**94-3171943**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania
18976-3622
(Address of principal executive offices)

(215) 488-9300
(Registrant's 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 x NO o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Accelerated filer x Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES oNO x

As of May 9, 2006, 61,199,429 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

Table of Contents

i

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

FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. The forward-looking statements include all matters that are not historical facts and include, without limitation: statements concerning our research and development programs and clinical trials; the possibility, timing and outcome 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; the period of time for which our existing resources will enable us to fund our operations; and anticipated cost savings and accounting charges arising out of our recent workforce reductions and corporate restructuring.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Examples of the risks and uncertainties include, but are not limited to:

- risk that financial conditions may change;
- risks relating to the progress of our research and development;
- the risk that we will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies);
- risk that we or our marketing partners will not succeed in developing market awareness of our products;
- risk that we or our marketing partners will not be able to attract or maintain qualified personnel;
- risk that the FDA or other regulatory authorities may delay consideration of any applications that we file;
- risk that the FDA or other regulatory authorities may not approve any applications we file;
- 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 materials suppliers and development partners to provide us with adequate supplies of drug substance and drug products for completion of any of our clinical studies;
- risks relating to our drug manufacturing operations;
- risks relating to the integration of our recently-acquired manufacturing operations into our existing operations;

- risks relating to our ability and the ability of our collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies;
- risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements;
- risks relating to the development of competing therapies and/or technologies by other companies;
- risks relating to our recent workforce reductions and corporate restructuring:
- risks relating to the impact of litigation that has been and may be brought against the Company and its officers and directors*;* and
- the other risks and uncertainties detailed in Part II, Item 1A: Risk Factors and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2005, and those described from time to time in our future reports filed with the Securities and Exchange Commission.

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

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Consolidated Balance Sheets
(in thousands, except per share data)

	March 31, 2006 (Unaudited)	December 31, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 32,226	$ 47,010
Restricted cash	680	647
Available-for-sale marketable securities	4,663	3,251
Prepaid expenses and other current assets	876	560
Total Current Assets	38,445	51,468
Property and equipment, net of accumulated depreciation	4,798	4,322
Other assets	218	218
Total Assets	$ 43,461	$ 56,008
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 8,168	$ 7,540
Credit facility, current portion	8,500	8,500
Capitalized leases and note payable, current portion	1,663	1,568
Total Current Liabilities	18,331	17,608
Capitalized leases and note payable, non-current portion	3,043	3,323
Other liabilities	239	239
Total Liabilities	21,613	21,170
Stockholders' Equity:		
Common stock, $0.001 par value; 180,000 shares authorized; 61,537 and 61,335 shares issued, 61,224 and 61,022 shares outstanding at March 31, 2006 and December 31, 2005, respectively.	61	61
Additional paid-in capital	242,776	240,028
Unearned portion of compensatory stock options	(173)	(230)
Accumulated deficit	(217,760)	(201,965)
Treasury stock (at cost; 313 shares)	(3,054)	(3,054)
Accumulated other comprehensive loss	(2)	(2)
Total Stockholders' Equity	21,848	34,838
Total Liabilities & Stockholders' Equity	$ 43,461	$ 56,008

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 March 31,	
	2006	**2005**
Revenues:		
Contracts and grants	$ ---	$ 61
Expenses:		
Research & development	7,613	5,120
General & administrative	8,682	4,270
Total Expenses	16,295	9,390
Operating Loss	(16,295)	(9,329)
Other income / (expense):		
Interest and other income	800	214
Interest expense	(300)	(201)
Other income / (expense), net	500	13
Net Loss	$ (15,795)	$ (9,316)
Net loss per common share - basic and diluted	$ (0.26)	$ (0.18)
Weighted average number of common shares outstanding - basic and diluted	61,170	50,784

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2006	**2005**
Cash flows from operating activities:		
Net loss	$ (15,795)	$ (9,316)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	215	214
Stock Issued related to 401(k) match	174	53
Stock-based compensation expense	1,903	70
Changes in:	-	-
Prepaid expenses and other current assets	(316)	(50)
Accounts payable and accrued expenses	628	(1,778)
Other assets	-	(50)
Net cash used in operating activities	(13,191)	(10,858)
Cash flows from investing activities:		
Purchase of property and equipment	(691)	(118)
Restricted cash	(33)	9
Purchases of marketable securities	(4,631)	(22,208)
Proceeds from sales or maturity of marketable securities	3,219	2,692
Net cash used in investing activities	(2,136)	(19,624)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	728	27,584
Proceeds from credit facility	-	2,571
Equipment financed through capital lease obligation	171	225
Principal payments under capital lease obligation	(356)	(205)
Net cash provided by financing activities	543	30,175
Net decrease in cash and cash equivalents	(14,784)	(307)
Cash and cash equivalents - beginning of period	47,010	29,264
Cash and cash equivalents - end of period	$ 32,226	$ 28,957
Supplementary disclosure of cash flows information:		
Interest paid	$ 296	$ 176
Non-cash transactions:		
Unrealized loss on marketable securities	--	(4)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION

The Company

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

The Company's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. The Company's lead product, Surfaxin® (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received two Approvable Letters from the FDA and is under review for approval in Europe by the European Medicines Agency (EMEA). The Company is preparing to conduct multiple Phase 2 pilot studies with Aerosurf™, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory failure.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, the Company recently completed and announced preliminary results of a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to potentially address Acute Lung Injury (ALI), cystic fibrosis and other respiratory conditions.

The Company is implementing a business strategy that includes: (i) undertaking actions intended to gain regulatory approvals for Surfaxin for RDS in premature infants, including analysis and remediation of recent regulatory matters and manufacturing issues (discussed in Note 7 --Subsequent Events, below); (ii) investing in development of SRT pipeline programs, including Aerosurf, primarily utilizing the aerosol generating technology rights licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis); (iii) continued investment in manufacturing capabilities at the manufacturing operations in New Jersey acquired by the Company in December 2005 and, potentially, additional facilities to be built or acquired by the Company for the production of surfactant drug products to meet anticipated clinical and commercial needs (if approved); and (iv) potentially entering into strategic partnerships for the development and commercialization of the Company's SRT product candidates.

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 month period ended March 31, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. 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, 2005.

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 presentations.

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 Company has a stock-based employee compensation plan. Prior to January 1, 2006, the Company accounted for this plan under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, (Opinion 25) and related interpretations, as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Generally, no stock-based employee compensation cost was recognized in the statements of operations, as options granted under the plan had an exercise price equal to the market value of the underlying common stock on the date of the grant. Effective January 1, 2006, the Company adopted the fair value recognition provisions of FASB Statement No. 123(R), *Share-Based Payment*, using the modified-prospective-transition method. Under that transition method, compensation cost recognized in the three months ended March 31, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair market value estimated in accordance with the original provisions of Statement 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based upon the grant-date fair value estimated in accordance with the provisions of Statement 123(R). Results from prior periods have not been restated.

As a result of adopting Statement 123(R) on January 1, 2006, the Company’s net loss for the three months ended March 31, 2006 was $1.7 million higher than if it had continued to account for share-based compensation under Opinion 25. Net loss per share for the three months ended March 31, 2006 would have been $0.23 per share if the Company had not adopted Statement 123(R), compared to reported net loss per share of $0.26. Of the total $1.7 million charge, $0.4 million was classified as research and development and $1.3 million was classified as general and administrative.

For comparative purposes, the following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of Statement 123(R) to options granted under the Company's stock option plan for the three months ended March 31, 2005. For purposes of this pro forma disclosure, the value of the option is estimated using a Black-Scholes-Merton option-pricing formula that uses the assumptions set forth under "Stock Incentive Plan" below and amortized to expense over the options' vesting periods.

(in thousands, except per share data)		**Three months ended March 31, 2005**
Net Loss, as reported	$	(9,316)
Net Loss per share, as reported	$	(0.18)
Add: Stock-based employee compensation expense included in reported net loss		___
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards		(619)
Pro forma net loss	$	(9,935)
Pro forma net loss per share	$	(0.20)

Stock Incentive Plan

The Company's 1998 Stock Incentive Plan (the Plan), which is shareholder-approved, permits the grant of share options and shares to its eligible employees, officers, consultants, independent advisors and non-employee directors for up to 10,075,000 shares of common stock. The Company believes that such awards better align the interests of its eligible participants with those of its shareholders. Option awards are granted with an exercise price equal to or greater than the market price of the Company's stock at the date of the grant. Although the terms of any award vary, option awards generally vest based upon three years of continuous service and have 10-year contractual terms.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option-pricing formula that uses assumptions noted in the following table. Expected volatilities are based upon the Company's historical volatility and other factors. The Company also uses historical data and other factors to estimate option exercises and employee terminations within the valuation model. The risk-free interest rates are based upon the U.S. Treasury yield curve in effect at the time of the grant.

	March 31, 2006	March 31, 2005
Expected volatility	81%	81%
Expected term (in years)	5 years	3.5 years
Risk-free rate	4.4%	3.7%
Expected dividends	0%	0%

A summary of option activity under the Plan as of March 31, 2006 and changes during the period is presented below:

(in thousands, except for weighted-average data)

Options	Shares	Weighted-Average Exercise Price	Weighed-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2006	8,440	$ 6.28		
Granted	904	7.08		
Exercised	(8)	3.15		
Forfeited or expired	(60)	6.97		
Outstanding at March 31, 2006	9,276	$ 6.35	7.31	$ 15,050
Vested at March 31, 2006	6,769	$ 6.63	6.86	$ 10,650
Exercisable at March 31, 2006	7,548	$ 6.23	6.84	$ 14,199

Based upon application of the Black-Scholes-Merton option-pricing formula described above, the weighted-average grant-date fair value of options granted during the three months ended March 31, 2006 was $4.70. The total intrinsic value of options exercised during the three months ended March 31, 2006 was $38,149.

A summary of the status of the Company's nonvested shares issuable upon exercise of outstanding options as of March 31, 2006 and changes during the period ended March 31, 2006 is presented below:

(in thousands, except for weighted-average data)

Option Shares	Amount	Weighted-Average Grant-Date Fair Value
Nonvested at January 1, 2006	1,907	$ 3.68
Granted	904	4.70
Vested	(252)	4.55
Forfeited	(53)	5.15
Nonvested at March 31, 2006	2,506	3.89

As of March 31, 2006, there was $6.8 million of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average vesting period of 2.3 years.

Note 4 - Comprehensive Loss

Total comprehensive loss was $15.8 million and $9.3 million for the three months ended March 31, 2006 and 2005, respectively. 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 - 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 three months ended March 31, 2006.

Note 7 - Subsequent Events

Manufacturing Issue

Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. Surfaxin is aseptically manufactured at our facility as a sterile, liquid dispersion. The manufacturing process to produce Surfaxin is complex, must be conducted in a sterile environment, and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients. Each batch of drug produced at the Company's manufacturing facility undergoes a stringent test regimen and a requisite number of batches per year are placed into a designed stability testing program consisting of specification testing conducted over multiple time intervals and storage conditions. A batch of drug product may fail to achieve the specified stability parameters. In April 2006, analysis of ongoing stability data from Surfaxin "process validation batches" indicated that certain stability parameters had not been achieved and, therefore, three additional Surfaxin process validation batches will likely have to be produced. These process validation batches were previously manufactured as a requirement for the Company's U.S. New Drug Application (NDA) regulatory approval and have been undergoing periodic stability testing. The Company anticipates a potentially significant delay in the U.S. regulatory approval process for Surfaxin for the prevention of RDS in premature infants. Though we are presently assessing the impact of these events on the European regulatory process, we expect that a similar delay in the Surfaxin European regulatory approval is likely..

Surfaxin Regulatory Approval

In April 2006, the Company received a second Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. The Approvable Letter is an official notification from the FDA and contains conditions that must be satisfied by the Company prior to obtaining final U.S. marketing approval. Specifically, the FDA is requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. Consistent with previous review, the FDA does not have any clinical or statistical comments.

The Company is currently analyzing the second Approvable Letter and preparing a comprehensive information package for the FDA addressing some of the issues in the second Approvable Letter. Once the analysis is completed and the manufacturing issues discussed above have been remediated, the Company will request a meeting with the FDA and submit the comprehensive information package. Upon receipt of the Company's request, procedurally, the FDA must respond within 14 days and the meeting must occur within 75 days of the written request. At the meeting, the Company will seek to clarify the issues identified by the FDA in the second Approvable Letter. Thereafter, and conditioned upon satisfactory Surfaxin process validation and stability, the Company will submit its formal response to the second Approvable Letter. The FDA will then advise the Company if it will accept the submitted response to the second Approvable Letter as a "complete" response and establish the time frame in which it will complete its review of the response. This is the second Approvable Letter received by the Company from the FDA since the Company's NDA for Surfaxin was filed in April 2004. The previously submitted responses to the first Approvable Letter were accepted by the FDA as a complete response in October 2005.

New Committed Equity Financing Facility (CEFF)

In April 2006, the Company entered into a new Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in which Kingsbridge committed to provide up to $50 million of capital to support the Company's future growth through the purchase of newly-issued shares of its common stock. The Company's previous Committed Equity Financing Facility, entered into with Kingsbridge in July 2004 (2004 CEFF) and which presently has capital of up to $47.6 million available, will automatically terminate upon effectiveness of the registration statement filed in connection with the new CEFF.

The Company will determine the exact timing and amount of any CEFF financings, subject to certain conditions. The CEFF allows the Company to raise capital, at the time and in amounts deemed suitable to the Company, during a three-year period once a related registration statement that was recently filed by the Company is declared effective by the Securities and Exchange Commission. The Company is not obligated to utilize any of the $50 million available under the CEFF. The purchase price of the shares sold to Kingsbridge under the new CEFF will be at a discount ranging from 6% to 10% of the volume weighted average of the price of our common stock for each of the eight trading days following our election to sell shares, or "draw down" under the CEFF. Kingsbridge is not obligated to purchase any shares at a stock price per share (before the applicable discount) that is less than $2.00.

In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase up to 490,000 shares of common stock at an exercise price of $5.6186 per share, which represents a 30% premium over the average of the closing bid prices of the Company's common stock for the five trading days preceding the signing of the agreement. The exercise term of the warrant is five years beginning with the six-month anniversary of the closing date of the agreement. The warrant must be exercised for cash, except in limited circumstances.

Corporate Restructuring

In order to lower the Company's cost structure and re-align its operations with business priorities, the Company has reduced its staff levels and has determined to conclude its Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants. The Company took these actions to respond to the anticipated significant delay in the regulatory approval and commercial launch of Surfaxin for RDS in premature infants.

Workforce Matters

On May 4, 2006, the Company announced a reduction in the number of its employees and a reorganized management structure. The workforce reduction totaled 55 employees, representing approximately 34% of the Company's workforce, and was focused primarily on its commercial infrastructure, the development of which is no longer in the Company's near-term plans. Included in the workforce reduction were three senior executives: Christopher J. Schaber, Ph.D.,Executive Vice President and Chief Operating Officer; Deni M. Zodda, Ph.D., Senior Vice President of Business Development; and Mark G. Osterman, Senior Vice President of Sales and Marketing. The affected employees are eligible for certain severance payments and continuation of benefits. The Company expects to take a one-time restructuring charge of approximately $4.5 to $5.0 million in the second quarter ending June 30, 2006 related to the staff reductions and the wind down of certain commercial programs The Company expects to realize annual expense savings of approximately $8.0 million from the reduction in work force and related operating expenses. Additionally, certain commercial programs are being discontinued and related costs will no longer be incurred. Such commercial program expenses totaled approximately $5.0 million over the past two fiscal quarters (fourth quarter of 2005 and first quarter of 2006).

In connection with the corporate restructuring and in order to retain and provide incentives to the Company's senior management, the Board of Directors has authorized amended and restated employment agreements for certain key executive officers, which generally extend the term of employment, and entering into new employment agreements with other key management employees. See also Part II, Item 5 - Other Information.

Surfaxin Phase 2 Clinical Trial for BPD

On May 9, 2006, the Company determined to conclude its Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD in premature infants. The Company plans to analyze the clinical data from this trial, report top-line results and submit these data for publication.

This determination is related to the Surfaxin regulatory and manufacturing issues that are anticipated to significantly delay the potential regulatory approval of Surfaxin for RDS and may potentially adversely affect the availability of Surfaxin drug product for this Phase 2 clinical trial.

Litigation

In early May 2006, a number of law firms issued press releases indicating that three putative shareholder class actions against the Company and its Chief Executive Officer, Robert J. Capetola, Ph.D., had been filed in the United States District Court for the Eastern District of Pennsylvania. The Company has been served recently with one such complaint and is assessing the purported class action claims at this time.

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 accompanying Consolidated Financial Statements (including the notes thereto) appearing elsewhere herein.

OVERVIEW

We are a biotechnology company developing our 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 two Approvable Letters from the FDA and is under review for approval in Europe by the EMEA. Our proprietary SRT is also being developed in an aerosolized form under the name Aerosurf, for the treatment of neonatal respiratory failure. We are preparing to conduct multiple Phase 2 pilot studies with Aerosurf, aerosolized SRT administered through nCPAP. In addition, also for premature infants, we have recently concluded early a Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD.

Based on recent events, we anticpate a potentially significant delay in the U.S. regulatory approval process for Surfaxin for the prevention of RDS in premature infants. Though we are presently assessing the impact of these events on the European regulatory process, we expect that a similar delay in the Surfaxin European regulatory approval process is likely. For a discussion of these events, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations.”

- In April 2006, analysis of ongoing stability data from Surfaxin “process validation batches”, which were produced as a requirement for our U.S. NDA, indicated that certain stability parameters had not been achieved and, therefore, three additional process validation batches will likely have to be produced. We are presently conducting an investigation to determine the cause and define the corrective actions needed to potentially remediate these manufacturing issues.

- In April 2006, we received a second Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants, requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. We are preparing a comprehensive information package and, after the manufacturing issues discussed above have been remediated, we will request a meeting with the FDA to clarify the issues identified in the second Approvable Letter. Thereafter, we will submit our formal response to the second Approvable Letter. The issues identified in the second Approvable Letter are not related to the clinical data from our multinational SELECT study, which demonstrates that Surfaxin was significantly more effective in the prevention of RDS and also improved survival (continuing through at least one year of life) and other outcomes versus the comparator surfactants.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, we recently completed and announced preliminary results of 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), cystic fibrosis, and other respiratory conditions.

Based upon our current expectations of the financial impact of the delay in the regulatory approval and commercial launch of Surfaxin for RDS, we undertook the following actions to lower our cost structure and re-align our operations with our business priorities.

- On May 4, 2006, we announced a reduction in personnel from 160 to 105 employees, representing approximately 34% of our workforce, and reorganized corporate management. We have also entered into new employment agreements intended to retain and provide incentives to our executive management and other key management employees.

- On May 9, 2006, we determined to conclude our Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD in premature infants. The Company plans to analyze the clinical data from this trial, report top-line results, and submit these data for publication. This determination is also related to the potentially adverse affect that recent events may have on the availability of Surfaxin drug product for this Phase 2 clinical trial.

The foregoing recent events have had a significant impact on our business strategy. We are now implementing a business strategy which includes:

- undertaking actions intended to gain regulatory approvals for Surfaxin for RDS in premature infants, including analysis and remediation of recent regulatory matters and manufacturing issues;

- investing in development of SRT pipeline programs, including Aerosurf, primarily utilizing the aerosol generating technology rights licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis);

    - use of our newly-acquired manufacturing facility, which is critical to the production of Surfaxin and our SRT clinical programs, to produce Surfaxin, other SRT formulations and aerosol development capabilities. We view our acquisition of manufacturing operations as an initial step in our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. Our strategy also includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products; and

- securing additional strategic partnerships for the development and commercialization of our proprietary SRT product candidates, including Surfaxin.

Since our inception, we have incurred significant losses and, as of March 31, 2006, we had an accumulated deficit of $217.8 million (including historical results of predecessor companies). The majority of our expenditures to date have been for research and development activities and, since 2005, also include significant general and administrative, primarily pre-commercialization, activities. Research and development expenses represent costs incurred for scientific and clinical personnel, clinical trials, regulatory filings and developing manufacturing capabilities. We expense research and development costs as they are incurred. General and administrative expenses consist primarily of Surfaxin pre-launch commercialization sales and marketing, executive management, financial, business development, legal and general corporate activities and related expenses. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations.”

Historically, we have funded our operations with working capital provided principally through public and private equity financings, debt arrangements and strategic collaborations. As of March 31, 2006, we had: (i) cash and investments of $37.6 million; (ii) $47.6 million available under the 2004 CEFF)with Kingsbridge, subject to the terms and conditions of that 2004 CEFF**;** (iii) a $9.0 million capital equipment lease financing arrangement with General Electric Capital Corporation (GECC), of which an aggregate of $6.5 million has been drawn during the life of the facility and, after giving effect to principal payments, $4.7 million of which was still payable; and (iv) a secured revolving credit facility of $8.5 million with PharmaBio Development Inc. (PharmaBio), of which the entire amount was drawn and payable. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources.”

RESEARCH AND DEVELOPMENT

Research and development expenses for the three months ended March 31, 2006 and 2005 were $7.6 million and $5.1 million, respectively. These costs are charged to operations as incurred and are tracked 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 reflects 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 (including a research funding and option agreement with The Scripps Research Institute which expired in February 2005).

Manufacturing Development

Manufacturing development primarily reflects costs incurred to develop current good manufacturing practices (cGMP) manufacturing capabilities in order to provide clinical and commercial scale drug supply. Manufacturing development activities include external contract manufacturing resources (including expenses associated with technology transfer and significant development costs associated with the implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process at the Totowa, NJ manufacturing facility that we acquired in December 2005), securing our own manufacturing capabilities and expanding the operations to meet production needs for our SRT pipeline, employee costs, depreciation, and expenses for the purchase of raw materials, 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 include 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 months ended March 31, 2006 and 2005:

(in thousands)	**Three Months Ended March 31,**	
Research and Development Expenses:	**2006**[1]	**2005**
Research and pre-clinical operations	$ 507	$ 929
Manufacturing development	2,507	1,390
Unallocated development - clinical and regulatory operations	2,523	1,639
Direct clinical trial expenses	2,076	1,162
Total Research and Development Expenses	**$ 7,613**	**$ 5,120**

(1) Included in expenses for the three months ended March 31, 2006 is a charge of $0.4 million associated with stock-based employee compensation in accordance with the provisions of FAS No. 123(R).

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 and 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations," below. Successful completion of development of our SRT is contingent on numerous risks, uncertainties and other factors, some of which are described in detail in the section entitled "Risk Factors".

These factors include:

- Completion of pre-clinical and clinical trials of our product candidates 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;
- Obtaining corporate partnerships for the development of our SRT pipeline, including Surfaxin.
- Performance of our third-party collaborators on whom we rely for supply of raw materials and related services necessary to manufacture our SRT drug product candidates, including Surfaxin;
- Timely resolution of the CMC and cGMP-related matters at our manufacturing operations in New Jersey with respect to Surfaxin and certain of our other SRTs presently under development, including matters that were noted by the FDA in its inspectional reports on Form FDA-483 and our recent drug stability testing issues;
- Successful manufacture of SRT drug product candidates, including Surfaxin, at our operations in New Jersey; and
- Obtaining additional manufacturing operations, 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 sufficient clinical supplies and material;
- Adverse medical events or side effects in treated patients;
- Lack of compatibility with complimentary technologies;
- 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 the value, financial condition and results of operations will be substantially harmed.

CORPORATE PARTNERSHIP AGREEMENTS

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In December 2005, we entered into a strategic alliance with Chrysalis Technologies (Chrysalis), a division of Philip Morris USA Inc., to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as ALI, neonatal respiratory failure, COPD, asthma, cystic fibrosis and others. The alliance unites two complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung.

Chrysalis has developed a proprietary aerosol generation technology that is being designed with the potential to enable targeted upper respiratory or deep lung delivery of therapies for local or systematic applications. The Chrysalis technology is designed to produce high-quality, low velocity aerosols for possible deep lung aerosol delivery. Aerosols are created by pumping the drug formulation through a small, heated capillary wherein the excipient system is substantially converted to the vapor state. Upon exiting the capillary, the vapor stream quickly cools and slows in velocity yielding a dense aerosol with a defined particle size. The defined particle size can be readily controlled and adjusted through device modifications and drug formulation changes.

The alliance focuses on therapies for hospitalized patients, including those in the neonatal intensive care unit (NICU), pediatric intensive care unit (PICU) and the adult intensive care unit (ICU), and can be expanded into other hospital applications and ambulatory settings. We and Chrysalis are utilizing their respective capabilities and resources to support and fund the design and development of integrated drug-device systems that can be uniquely customized to address specific respiratory diseases and patient populations. Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products. We have exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Generally, Chrysalis will receive a tiered royalty on product sales: the base royalty generally applies to aggregate net sales of less than $500 million per contract year; the royalty generally increases on aggregate net sales in excess of $500 million per contract year, and generally increases further on aggregate net sales of alliance products in excess of $1 billion per contract year.

Our lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nCPAP to treat premature infants in the NICU at risk for respiratory failure. Our lead adult program utilizing the Chrysalis technology is the development of aerosolized SRT administered as a prophylactic for patients in the hospital at risk for Acute Lung Injury (ALI).

Laboratorios del Dr. Esteve, S.A.

In December 2004, we reached an agreement with Esteve to restructure our pre-existing strategic alliance for the development, marketing and sales of our products in Europe and Latin America. Under the revised alliance, we regained full commercialization rights in key European markets, Central America and South America for SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults. Esteve will focus on Andorra, Greece, Italy, Portugal, and Spain, and now has development and marketing rights to a broader portfolio of potential SRT products. Esteve will pay us a transfer price on sales of Surfaxin and other SRT. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the revised territory. Esteve has agreed to make stipulated cash payments to us upon its achievement of certain milestones, primarily upon receipt of marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products by conducting and funding development performed in the revised territory.

In October 2005, Esteve sublicensed the distribution rights to Surfaxin in Italy to Dompe Farmaceitici Spa (Dompe), a privately owned Italian company. Under the sublicense agreement, Dompe will be responsible for sales, marketing and distribution in Italy of Surfaxin.

PLAN OF OPERATIONS

The Company has incurred substantial losses since inception and expects to continue to expend substantial amounts for continued product research, development, manufacturing, and general business activities. We anticipate that during the next 12 to 24 months:

Research and Development

We will focus our research, development and regulatory activities in an effort to develop a 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 applicable risks discussed in the “Risk Factors” section herein and those contained in our most recent Annual Report on Form 10-K.

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.

In April 2006, we received a second Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. Specifically, the FDA requested certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. Consistent with previous review, the FDA did not have any clinical or statistical comments. We are currently analyzing the second Approvable Letter and preparing a comprehensive information package for the FDA addressing some of the issues in the second Approvable Letter. Once the analysis is completed, and conditioned upon the satisfactory resolution of our Surfaxin manufacturing issues (discussed below), we will request a meeting with the FDA and submit the comprehensive information package. Upon receipt of our request, procedurally, the FDA must respond within 14 days and the meeting must occur within 75 days of the written request. At the meeting, we will seek to clarify the issues identified by the FDA in the second Approvable Letter. Thereafter, conditioned upon satisfactory Surfaxin process validation and stability, we will submit our formal response to the second Approvable Letter. The FDA will then advise us if it

will accept the submitted response to the second Approvable Letter as a “complete” response and the time frame in which it will complete its review.

In April 2006, analysis of ongoing stability data from Surfaxin process validation batches indicated that certain stability parameters had not been achieved and, therefore, additional process validation batches will likely have to be produced. These process validation batches were previously manufactured as a requirement for the Company's U.S. NDA regulatory approval and have been undergoing periodic stability testing. We anticipate a potentially significant delay in the U.S. regulatory approval process for Surfaxin for RDS in premature infants. Though we are presently assessing the impact of these events on the European regulatory process, we expect that a similar delay in the Surfaxin European regulatory approval process is likely.

With respect to our manufacturing problems, we have initiated a detailed investigation to determine the cause of the failure of our Surfaxin process validation to meet the designated stability parameters in our stability testing program. Following the conclusion of our investigation, we will have to implement a remediation program (the length of which cannot be determined at this time), manufacture additional process validation batches and subject them to the stability testing program (which we anticipate will require a minimum of six months after the new process validation batches have been manufactured). At this time, we cannot predict when the potential approval and commercial launch of Surfaxin in the United States and Europe will occur.

We have filed a Marketing Authorization Application (MAA) with the EMEA for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. Activities associated with this regulatory filing are ongoing. We have received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA for Surfaxin for the prevention and rescue treatment of Respiratory Distress Syndrome in premature infants. We submitted a written response to all of the CHMP's outstanding issues in April 2006 and, according to standard CHMP procedures, the Committee is expected to make a recommendation on whether to grant a Marketing Authorization for Surfaxin and issue a formal Opinion in late July 2006. We are presently assessing the impact our recent manufacturing issues will have on the Surfaxin European regulatory approval process, including the likelihood of a significant delay.

On May 9, 2006, with enrollment totaling approximately 130 patients, the Company determined to conclude early its Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD in premature infants. This double-blind, controlled Phase 2 clinical trial was intended to enroll up to 210 very low birth weight premature infants born at risk for developing BPD. The study's objective is to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD. In January 2006, the FDA granted Fast Track designation to Surfaxin for prevention and treatment of BPD in premature infants and, in October 2005, the Office of Orphan Products Development of the FDA granted Orphan Drug designation to Surfaxin for the treatment of BPD. The Company plans to perform a comprehensive analysis of the clinical data from this trial, report top-line results and submit these data for publication.

Aerosurf is our precision-engineered aerosolized SRT administered via nCPAP intended to treat premature infants at risk for respiratory failures. In September 2005, we 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 using a commercially-available aerosolization device 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 that the treatment was generally safe and well tolerated.

In December 2005, we entered into a strategic alliance with Chrysalis. The alliance unites two highly complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung. Through this alliance, we gained exclusive rights to their aerosolization technology for use with pulmonary surfactants for all respiratory diseases. Our lead neonatal program utilizing the Chrysalis technology is Aerosurf administered via nCPAP to treat premature infants in the NICU at risk for neonatal respiratory disorders. We anticipate initiating a pilot Phase 2 clinical study of Aerosurf utilizing the Chrysalis aerosolization technology late 2006 or early 2007, which may be

impacted by the remediation of our manufacturing issues discussed above.

SRT for Critical Care and Hospital Indications

In March 2006, we completed and announced preliminary results of a Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults using our precision-engineered surfactant delivered via bronchoscopic segmental lavage (Surfactant Lavage). The ARDS Phase 2 clinical trial was an open-label, controlled, multi-center, international study of Surfactant Lavage for the treatment of ARDS in adults that was designed to enroll up to 160 patients. Total enrollment in the trial was 124 patients.

The objective of the Surfactant Lavage was to restore functional surfactant levels in the patients' lungs, thereby improving oxygenation in order to remove critically ill patients from mechanical ventilation sooner. Comprehensive analysis of the data from this trial is ongoing and we continue to assess safety and tolerability. Following this analysis, we plan to submit these data for publication in a peer review journal. We plan to seek potential partners, with which we can apply the scientific and clinical observations generated from this trial to support the design of potential future trials to treat ARDS.

We are also evaluating the development of aerosol formulations of SRT to potentially address ALI, cystic fibrosis, and other respiratory conditions. In December 2005, we entered into a strategic alliance with Chrysalis to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. Our lead adult program utilizing the Chrysalis technology is the development of aerosolized SRT administered as a prophylactic for patients in the hospital at risk for Acute Lung Injury (ALI). Given our current priority to focus on developing the SRT pipeline for the NICU, we will be assessing the timing and further prioritization of these adult programs.

Manufacturing

Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. Surfaxin is aseptically manufactured at our facility as a sterile, liquid dispersion. The manufacturing process to produce Surfaxin is complex, must be conducted in a sterile environment, and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients.

We will invest in and support our manufacturing strategy for the production of our precision-engineered SRT to meet anticipated clinical needs and, if approved, commercial needs in the United States, Europe and other markets:

Manufacturing in our New Jersey Operations

In December 2005, we purchased the manufacturing operations of Laureate Pharma (our contract manufacturer at that time) that are critical to the production of Surfaxin and our SRT clinical programs. This facility is our only validated clinical facility in which we produce clinical grade material of our drug substance. We will use this pharmaceutical manufacturing and development facility for the production of Surfaxin and for the development and enhanced formulations of Surfaxin and the development of aerosol formulations including Aerosurf. In connection with our purchase of the facility, we entered into a transitional services arrangement under which Laureate will provide us with certain limited manufacturing-related support services through December 2006.

In April 2006, analysis of ongoing stability data from Surfaxin "process validation batches" indicated that certain stability parameters had not been achieved and, therefore, three additional process validation batches will likely have to be produced. These process validation batches were previously manufactured as a requirement for the Company's U.S. NDA regulatory approval and have been undergoing periodic stability testing. We anticipate a potentially significant delay in the U.S. regulatory approval process for Surfaxin for RDS in premature infants. Though we are presently assessing the impact of these events on the European regulatory process, we expect that a similar delay in the Surfaxin European regulatory approval process is likely. We are investing in manufacturing and regulatory activities intended to gain regulatory approvals for Surfaxin for RDS in premature infants, including analysis and remediation of recent regulatory matters and manufacturing issues.

Longer-Term Manufacturing Capabilities

We view the recent acquisition of a New Jersey manufacturing facility as an initial step of our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. The lease for our New Jersey manufacturing operations is through December 2014. In addition to the customary terms and conditions, the lease contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and, in the earlier years, payment to us of significant early termination amounts, subject to certain conditions. Taking into account this early termination option for our Totowa, NJ, facility, our long-term strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products.

Aerosol Devices and Related Componentry

For our planned clinical trials, we plan on utilizing third-party contract manufacturers, suppliers and assemblers for the aerosolization devices and related componentry for our aerosol SRT product candidates.

See the applicable risks discussed in the "Risk Factors" section herein and those contained in our most recent Annual Report on Form 10-K.

General and Administrative

We intend to invest in general and administrative resources primarily to support our legal requirements, intellectual property portfolios (including building and enforcing our patent and trademark positions), our business development initiatives, financial systems and controls, management information technologies, and general management capabilities.

We will need to generate significant revenues from product sales, related royalties and transfer prices to achieve and maintain profitability. Through March 31, 2006, 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 suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through March 31, 2006, we had not generated taxable income. On December 31, 2005, net operating losses available to offset future taxable income for Federal tax purposes were approximately $187.0 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 $3.8 million at December 31, 2005. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2009 through 2024.

RESULTS OF OPERATIONS

For the quarter ended March 31, 2006, the net loss was $15.8 million, or $0.26 per share, on 61.2 million weighted average common shares outstanding, compared to a net loss of $9.3 million, or $0.18 per share, on 50.8 million weighted average shares outstanding for the same period in 2005.

We adopted Financial Accounting Standards No. 123(R) (“FAS 123(R)”) on January 1, 2006 using the modified prospective method, which resulted in the recognition of stock compensation expenses in the statement of operations during the quarter ended March 31, 2006 without adjusting the prior year first quarter. The net loss includes $1.7 million, or $0.03 per share, of stock-based compensation expenses as a result of our adoption of FAS 123(R). Excluding this charge, the net loss for the quarter ended March 31, 2006 was $14.1 million, or $0.23 per share.

Revenues

Revenue for the three months ended March 31, 2006 and 2005 was $0 and $61,000, respectively. The revenue in 2005 was associated with our corporate partnership agreement with Esteve to develop, market and sell Surfaxin in Southern Europe.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2006 and 2005 were $7.6 million and $5.1 million, respectively, and the increase as compared to the same prior year period primarily reflects:

(i) manufacturing development activities to support the production of clinical and commercial drug supply for our SRT programs, including Surfaxin, in conformance with current Good Manufacturing Practices (cGMPs). Expenses related to manufacturing development activities were $2.5 million and $1.4 million for the three months ended March 31, 2006 and 2005, respectively. The increase is primarily associated with the ownership of our NJ manufacturing operations which we purchased from Laureate Pharma, Inc. (our contract manufacturer at that time) in December 2005.

(ii) U.S. and European regulatory activities associated with Surfaxin for RDS; (ii) clinical activities for the Phase 2 trial for ARDS in adults and the Phase 2 trial for BPD in premature infants; and (iii) development activities related to Aerosurf for Neonatal Respiratory Disorders. These research and development expenses, excluding manufacturing development activities, were $5.1 million and $3.7 million for the three months ended March 31, 2006 and 2005, respectively. Additionally, there was a charge of $0.3 million, for the three months ended March 31, 2006, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R.

(iii) development activities related to Aerosurf for Neonatal Respiratory Disorders. These research and development expenses, excluding manufacturing development activities, were $5.1 million and $3.7 million for the three months ended March 31, 2006 and 2005, respectively. Additionally, there was a charge of $0.3 million, for the three months ended March 31, 2006, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2006 and 2005 were $8.7 million and $4.3 million, respectively. General and administrative expenses consist primarily of the costs 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 months ended March 31, 2006 as compared to the same prior year period primarily reflects:

(i) pre-launch commercialization activities related to building a United States commercial infrastructure to market our SRT to address respiratory disorders in the NICU. Expenditures are for sales, marketing and medical affairs activities and, for the three months ended March 31, 2006 and 2005, were $5.0 million and $2.4 million, respectively. Additionally, there is a charge of $0.3 million, for the three months ended March 31, 2006, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R.

(ii) business administrative expenses related to building management and systems for 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. Such expenses were $3.7 million and $1.9 million for the three months ended March 31, 2006 and 2005, respectively. Additionally, there is a charge of $1.0 million, for the three months ended March 31, 2006, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R.

Other Income/(Expense)

Other income and (expense) for the three months ended March 31, 2006 and 2005 was $500,000 and $13,000, respectively.

Included in other income for the three months ended March 31, 2006 was $280,000 of proceeds from the sale of our State of Pennsylvania research and development tax credits.

Interest income for the three months ended March 31, 2006 and 2005 was $520,000 and $214,000, respectively. The increase is primarily due to a general increase in earned market interest rates.

Interest expense for the three months ended March 31, 2006 and 2005 was $300,000 and $201,000, 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

Working Capital

Cash is required to fund our working capital needs, to purchase capital assets, and to pay our debt service, including principal, interest and capital lease obligations. We have funded our cash requirements primarily through the issuance of equity securities and the use of credit and capital lease facilities. We plan to fund our future cash requirements through:

- the issuance of equity and debt financings;
- payments from potential strategic collaborators, including license fees and sponsored research funding;
- sales of Surfaxin, if approved;
- capital lease financings; and
- interest earned on invested capital.

After taking into account the recently taken cost containment measures, we believe our current working capital is sufficient to meet planned activities into late 2006, before taking into account any amounts that may be available through the 2004 CEFF or the new CEFF (as described below). We anticipate using, if available, the new CEFF to support working capital needs in 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, and satisfy debt obligations. Working capital requirements will depend upon numerous factors, including, without limitation, the progress of our research and development programs, clinical trials, the timing and cost of obtaining regulatory approvals, remediation of manufacturing issues, levels of resources that we devote to the further development of manufacturing and product development capabilities, technological advances, status of competitors, ability to establish collaborative arrangements with other organizations, the ability to defend and enforce intellectual property rights, litigation and regulatory activities, and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

Cash, Cash Equivalents and Marketable Securities

As of March 31, 2006, we had cash, cash equivalents, restricted cash and marketable securities of $37.6 million, as compared to $50.9 million as of December 31, 2005, a decrease of $13.3 million. The decrease primarily consists of cash used in operating and investing activities of $13.9 million, offset by $0.7 million of proceeds from the exercise of stock options and warrants.

Committed Equity Financing Facility

In July 2004, we entered into the 2004 CEFF with Kingsbridge, pursuant to which Kingsbridge committed to finance up to $75.0 million of capital for newly-issued shares of Common Stock. In connection with the 2004 CEFF, we issued a Class B Investor warrant to Kingsbridge to purchase up to 375,000 shares of Common Stock at an exercise price equal to $12.0744 per share. The warrant, which expires in January 2010, must be exercised for cash, except in limited circumstances, for total proceeds equal to approximately $4.5 million, if exercised. As of March 31, 2006, the Class B Investor Warrant had not been exercised in whole or in part.

On April 17, 2006, we entered into a new CEFF with Kingsbridge, by way of a Common Stock Purchase Agreement, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to $50 million or up to 11,677,047 shares of our common stock. Upon effectiveness of the new CEFF, our 2004 CEFF, which presently has capital of up to $47.6 million available subject to certain conditions thereof, will automatically terminate.

This new CEFF allows us to raise capital, subject to certain conditions that we must satisfy, at the time and in amounts deemed suitable to us, during a three-year period once a related registration statement is filed by us and declared effective by the Securities and Exchange Commission. We are not obligated to utilize any of the $50 million available under the new CEFF.

The purchase price of the shares sold to Kingsbridge will be at a discount ranging from 6 to 10 percent of the volume weighted average of the price of our common stock (VWAP) for each of the eight trading days following our election to sell shares, or “draw down” under the CEFF. The discount on each of these eight trading days will be determined as follows:

VWAP*	Percent of VWAP (Applicable Discount)	
Greater than $10.50 per share	94%	(6)%
Less than or equal to $10.50 but greater than $7.00 per share	92%	(8)%
Less than or equal to $7.00 but greater than or equal to $2.00 per share	90%	(10)%

* As such term is set forth in the Common Stock Purchase Agreement.

During the eight trading day pricing period for a draw down, if the VWAP for any one trading day is less than the greater of (i) $2.00 or (ii) 85 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period, the VWAP from that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount we had initially specified.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. Each draw down is limited to the lesser of 2.5 percent of the closing price market value of our outstanding shares of common stock at the time of the draw down or $10 million. Unless Kingsbridge agrees otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next draw down pricing period. Kingsbridge is not obligated to purchase shares at prices below $2.00 per share, before taking into account the applicable discount. In addition, Kingsbridge may terminate the CEFF under certain circumstances, including if a material adverse effect relating to our business continues for ten trading days after notice of the material adverse effect.

In connection with the new CEFF, we issued a Class C Investor Warrant to Kingsbridge to purchase up to 490,000 shares of common stock at an exercise price of $5.6186 per share, which is fully exercisable beginning October 17, 2006 and for a period of five years thereafter. The warrant must be exercised for cash, except in limited circumstances.

Potential Financings under the October 2005 Universal Shelf Registration Statement

In October 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 $100.0 million of our debt or equity securities. In December 2005, we completed a registered direct offering of 3,030,304 shares of our common stock to select institutional investors resulting in gross proceeds to us of $20.0 million.

The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately $80.0 million of equity or debt securities. There can be no assurance, however, that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include the progress of our research and development activities, investor perception of our prospects and the general condition of the financial markets, among others.

Debt Facilities

Credit Facility with Quintiles Transnational Corp.

We entered into a collaboration arrangement with Quintiles Transnational Corp. (Quintiles), in 2001, to provide certain commercialization services in the United States for Surfaxin for the treatment of RDS in premature infants and MAS in full-term infants. In connection with the commercialization agreement, PharmaBio, Quintiles strategic investment group, extended to us a secured, revolving credit facility of $8.5 to $10.0 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States. The interest rate is the greater of 8% or prime rate plus 2% annually and payments are due quarterly in arrears. As of March 31, 2006, $8.5 million was outstanding under the credit facility and is classified as a current liability. Outstanding principal and interest due under the credit facility are due and payable as a balloon payment on December 31, 2006.

Capital Lease and Note Payable Financing Arrangements with General Electric Capital Corporation

Our primary capital lease financing arrangement is with the Life Science and Technology Finance Division of General Electric Capital Corporation (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. The capital lease is secured by the related assets. Subject to certain conditions, this arrangement provides for financing of up to $9 million. On May 9, 2006, GECC agreed to amend the arrangement, which would have expired April 30, 2006, such that the funds are now available through October 2006**,** subject to certain conditions and in consideration of certain undertakings on our part, including a pledge of certain proceeds of certain components of our intellectual property and an agreement not to pledge, with certain exceptions, any interest in our intellectual property. Laboratory and manufacturing equipment is financed over 48 months and all other equipment is financed over 36 months. Interest rates vary in accordance with changes in the three and four year treasury rates. As of March 31, 2006, $4.7 million is outstanding ($1.7 million classified as current liabilities and $3.0 million as long-term liabilities) and $2.5 million remains available for future use, subject to certain conditions.

Lease Agreements

We maintain facility leases for our operations in Pennsylvania, New Jersey 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 lease a 21,000 square foot pharmaceutical manufacturing and development facility in Totowa, NJ that is specifically designed for the production of sterile pharmaceuticals in compliance with cGMP requirements. The lease expires in December 2014 with total aggregate payments of $1.4 million ($150,000 per year). The lease contains an early termination option, first beginning in December 2009. The early termination option can only be exercised by the landlord upon a minimum of two years prior notice and payment of significant early termination amounts to us, subject to certain conditions.

We also lease approximately 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 May 2006, subject to monthly extensions.

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.

Future Capital Requirements

Unless and until we can generate significant cash from our operations, we expect to continue to require substantial additional funding to conduct our business, including our manufacturing and research and product development activities and to repay our indebtedness. 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 CEFF financing arrangements with Kingsbridge and our capital lease financing arrangement with General Electric Capital Corporation, 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 when needed or on terms acceptable to us, if at all. If we fail to receive additional funding or enter into collaborative ventures, we may have to reduce significantly the scope of or discontinue our planned research and development activities, which could significantly harm our financial condition and operating results.

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

On May 1, 2006, Hal Unschuld, individually and purportedly on behalf of a class of the Company's investors who purchased the Company's publicly traded securities between December 28, 2005 and April 25, 2006, filed an action in the United States District Court for the Eastern District of Pennsylvania against the Company and the Company's Chief Executive Officer, Robert J. Capetola (the "Unschuld Action"). This action alleges violations of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), Rule 10b-5 promulgated thereunder and Section 20(a) of the Exchange Act in connection with various public statements made by the Company and seeks an order that the action may proceed as a class action and an award of compensatory damages in favor of the plaintiff and the other class members in an unspecified amount, together with interest and reimbursement of costs and expenses of the litigation and other equitable or injunctive relief.

The Company has been notified that two additional class actions seeking the same relief have since been filed in the United States District Court for the Eastern District of Pennsylvania, although the Company has not been served with a complaint in these actions.

Additional actions may be filed against the Company. Although we cannot predict the outcome of such actions, an adverse result could have a potentially material adverse effect on the Company's business, results of operations and financial condition.

Item 1A. Risk Factors

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.

The risk factors set forth below have been revised based on recent events related to the Company and described elsewhere in this report. These risk factors should be read together with the factors discussed in Part I, Item 1A - Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2005.

The risks described in this report and in our Annual Report on Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Refocusing our business subjects us to risks and uncertainties.

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

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

We have undertaken and expect to continue to undertake cost-savings initiatives. However, we cannot assure you that we will realize on-going cost savings or any other benefits from these initiatives. Even if we realize the benefits of our cost savings initiatives, any cash savings that we achieve may be offset by other costs, such as costs related to

ongoing development activities and pilot studies. Staff reductions may reduce our workforce below the level needed to effectively manage our business and service our development programs. Our failure to realize the anticipated benefits of our cost-savings initiatives could have a material adverse effect on our business, results of operations and financial condition.

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

We currently have no products approved for marketing and sale and are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products. Our long-term viability will be impaired if we are unable to obtain regulatory approval for, or successfully market, our product candidates.

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development before their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of March 31, 2006, we have an accumulated deficit of approximately $218 million and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

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

To sell Surfaxin or any of our other products under development, we must receive regulatory approvals for each product. The FDA and foreign regulators extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish the safety and effectiveness of each product and the confirmation by the FDA and foreign regulators that, in manufacturing the product, we maintain good laboratory and manufacturing practices during testing and manufacturing. Even if favorable testing data is generated by clinical trials of drug products, the FDA or EMEA may not accept or approve an NDA or MAA filed by a pharmaceutical or biotechnology company for such drug product. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products.

We have filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued a Form 483 to our then contract manufacturer, Laureate Pharma, Inc. citing inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with current good manufacturing practices (cGMPs). The FDA issued an Approvable Letter to us in February 2005 regarding our NDA. To address the Form 483 inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin. In October 2005, the FDA accepted our responses to the Approvable Letter as a complete response thereby establishing April 2006 as its target to complete its review of our NDA. In April 2006, analysis of ongoing stability data from Surfaxin "process validation batches", which were produced as a requirement for our U.S. NDA, indicated that certain stability parameters had not been achieved and, therefore, three additional process validation batches will likely have to be produced. We are presently conducting an investigation to determine the cause and define the corrective actions needed to potentially remediate these manufacturing issues. Also in April 2006, the FDA issued a second Approvable Letter to us, requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. We are preparing a comprehensive information package and, after the manufacturing issues discussed above have been remediated, we will request a meeting with the FDA to clarify the issues identified in the second Approvable Letter. Thereafter, we will submit our formal response to the second Approvable Letter. At that time, the FDA will advise us of the time frame in which it will complete its review and advise us if it will accept our response to the second Approvable Letter as a complete response. After the FDA has accepted our response as a complete response, the FDA might still delay its approval of our NDA or reject our NDA, which would have a material adverse effect on our business.

We have filed an MAA with the EMEA for clearance to market Surfaxin for the prevention of RDS in premature infants in Europe. In February 2006, we received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA. We submitted a written response to all of the CHMP's outstanding issues in April 2006 and, according to standard CHMP procedures, the Committee is expected to make a recommendation on whether to grant a Marketing Authorization for Surfaxin and issue a formal Opinion in late July 2006. The EMEA, however, may delay its decision or not complete the review or may reject the MAA. In addition, we do not know at this time whether the failure of process validation batches (which are a part of the U.S. NDA) to achieve stability parameters in periodic stability testing will have any impact on the Surfaxin European regulatory approval process, but such approval is likely to be delayed.

See also Item 1: "Financial Statements: Note 7 - Subsequent Events" and Item 2: "Management's Discussion and Analysis of Financial Condition and Results of Operation - Overview and Plan of Operations."

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

The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. The FDA or a foreign regulator 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 or a foreign regulator may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions.

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

We submitted an NDA to the FDA for Surfaxin for the prevention of RDS in premature infants. In April 2006, we received a second Approvable Letter from the FDA, which contained a list of inspectional observations on Form 483. Thereafter, we learned that analysis of ongoing stability data from Surfaxin "process validation batches", which are a part of our NDA, indicated that certain stability parameters had not been achieved and, therefore, three additional Surfaxin process validation batches will likely have to be produced. These events are expected to significantly delay the review of our NDA. When we have completed and submitted our response to the second Approvable Letter and remediated our manufacturing issues, the FDA may request additional information from us, including data from additional clinical trials. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to obtain FDA approval or further delay associated with the FDA's review process would adversely impact our ability to commercialize our lead product.

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

Clinical trials generally take two to five years or more to complete. Like many biotechnology companies, we may suffer significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials or in preliminary findings for such clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials. The timing and completion of current and planned clinical trials of our product candidates depend on, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

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

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

It is also possible that the FDA or foreign regulators could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If we or any regulator believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not reach agreement with the FDA or a foreign regulator on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and foreign regulators on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials.

In addition to our efforts to commercialize Surfaxin for the prevention of RDS in premature infants, we recently concluded a Phase 2 clinical trial to address ARDS in adults. As a consequence of our Surfaxin regulatory and manufacturing issues that are anticipated to significantly delay the potential regulatory approval of Surfaxin for RDS inpremature infants and may potentially adversely affect the availability of Surfaxin drug product, we also determined to conclude early our ongoing Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD in premature infants. This Phase 2 clinical trial was being conducted to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD in premature infants. We are preparing to conduct multiple Phase 2 pilot studies with Aerosurf for the potential treatment of premature infants in the NICU suffering from neonatal respiratory failure.

See also Item 1: “Financial Statements: Note 7 - Subsequent Events” and Item 2: “Management’s Discussion and Analysis of Financial Condition and Results of Operation - Overview and Plan of Operations.”

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

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

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

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

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, 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 will need additional capital and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution.

We will need substantial additional funding to conduct our presently planned research and product development activities. Based on our current operating plan, we believe that our currently available working capital will be adequate to satisfy our capital needs into 2007, before taking into account any amounts that may be available through the CEFF. 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 CEFFs with Kingsbridge, our revolving credit facility with PharmaBio and our capital equipment lease financing arrangement with GECC. Kingsbridge has the right under certain circumstances to terminate the new CEFF, including as a consequence of a material adverse effect, including, potentially, our recent issues with product stability testing. Moreover, Kingsbridge is not obligated to purchase shares under the CEFF if our per-share stock price is below $2.00. If we seek additional financing, such additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations. See also "Risk Factors: Our Committed Equity Financing Facility may have a dilutive impact on our stockholders."

Furthermore, if the market price of our common stock declines as a result of the dilutive aspects of such potential financings, we could cease to meet the financial requirements to maintain the listing of our securities on The Nasdaq National Market. See “Risk Factors: The market price of our stock may be adversely affected by market volatility.”

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

There are 12,167,047 shares of our common stock that are reserved for issuance under the new CEFF arrangement we entered into with Kingsbridge on April 17, 2006, 490,000 of which are issuable upon exercise of the Class C Investor Warrant we issued to Kingsbridge. There are 375,000 shares of common stock that are reserved for issuance upon exercise of the Class B Investor Warrant we issued to Kingsbridge under the 2004 CEFF. The issuance of shares of our common stock under the CEFFs and upon exercise of the warrants 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 new 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.

On July 7, 2004 we entered into the 2004 CEFF with Kingsbridge by way of a Common Stock Purchase Agreement, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to $75 million of our common stock. In 2005, $20.2 million was successfully raised under the 2004 CEFF in two separate financings over 15 day periods in September and November, respectively. On the effective date of the registration statement which we filed in connection with the new CEFF (described above), the 2004 CEFF will be terminated; provided, however, that the related registration rights agreement executed in connection with the 2004 CEFF and the Class B Investor Warrant shall remain in effect. We anticipate using the new CEFF during 2006 to support corporate manufacturing and development and research activities.

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

We may not be able to meet the conditions we are required to meet under the CEFF and we may not be able to access any portion of the up to $50 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.

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

Our strategy for the completion of the required development and clinical testing of our products and for the marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. Our collaboration arrangement with Esteve for Surfaxin and certain other of our product candidates is 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 of RDS in premature 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. Accordingly, we may need to enter into additional collaboration agreements and our success may depend upon obtaining additional collaboration partners. In addition, we may depend on our collaborators' expertise and dedication of sufficient resources to develop and commercialize our proposed products.

In December, 2005, we entered into a Strategic Alliance Agreement with Chrysalis to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. Under the agreement, we have exclusive rights to Chrysalis' proprietary aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Chrysalis will assist with the development of certain combination drug-device surfactant products, and provide certain additional consultative services to us in connection with combination drug-device surfactant products, provided that certain terms and conditions are satisfied. Additionally, Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products.

We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See "Risk Factors: We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates."

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

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

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

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

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

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

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

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

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

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

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

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

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

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of our key personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. In order to lower the Company's cost structure and re-align its operations with business priorities, on May 4, 2006, we announced a reduction in the number of our employees and a reorganized corporate structure. The workforce reduction totaled 55 employees, representing approximately 34% of the Company's workforce, and was focused primarily on commercial infrastructure, the development of which is no longer in our near-term plans. Included in the workforce reduction were three senior executives. The duties and responsibilities of these executives have been transferred within the management organization and the Company presently does not expect to fill those positions in the near-term. As a consequence of this reduction in force, the Company's dependence on our remaining management team is increased. If we find it necessary or advisable to hire additional managers, a portion of the expected cost savings from our recent restructuring might not be realized.

To retain and provide incentives to certain of our key continuing executives, we recently entered into amended and new employment agreements with our executive management and other officers, which agreements provide for employment for a stated term, subject to automatic renewal, severance payments in the event of termination of employment, enhanced severance benefits in the event of a change of control and equity incentives in the form of stock and option grants**.** Although these employment agreements generally include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the applicable noncompete provisions can be difficult and costly to monitor and enforce. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key-man life insurance.

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

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

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

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

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

Our common stock is listed for quotation on The Nasdaq National Market. During the twelve month period ended April 30, 2006, the price of our common stock has ranged from $2.18 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 twelve month period ended April 30, 2006, the average daily trading volume in our common stock was approximately 777,000 shares and the average number of transactions per day was approximately 2,300. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of The Nasdaq National Market. If the common stock were no longer listed on The Nasdaq National Market, investors might only be able to trade on the Nasdaq Capital 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 March 31, 2006, we had 61,223,973 shares of common stock issued and outstanding.

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

Additionally, there are 375,000 shares of our common stock that are currently reserved for issuance under the 2004 CEFF and, assuming the effectiveness of the new CEFF, 12,167,047 shares of our common stock that are currently reserved for issuance under the new CEFF. See “Risk Factors: Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.”

As of March 31, 2006, up to 11,639,777, 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.

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

We are potentially susceptible to litigation. For example, as a public company, we are subject to claims asserting violations of securities laws, as well as derivative actions. In particular, in early May 2006, a number of law firms issued press releases indicating that a putative shareholder class action against the Company and its Chief Executive Officer, Robert J. Capetola, Ph.D., has been filed in the United States District Court for the Eastern District of Pennsylvania. We have been served with a complaint and are assessing the class action claims at this time. We have been advised that two additional complaints have been filed, although we have not been served in those actions. Additional actions may be filed against the Company. Although we cannot predict the outcome of any of these actions, an adverse result in one or more of them could have a potentially material adverse effect on the Company’s business, results of operations and financial condition.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In the quarter ended March 31, 2006, pursuant to the exercise of outstanding warrants and options, we issued an aggregate of 108,316 shares of common stock at various exercise prices ranging from $1.50 to $6.875 per share for a aggregate consideration equal to $714,000. We claimed 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.

In the quarter ended March 31, 2006, we issued 69,500 shares of restricted stock to certain employees at no cost. We claimed the exemption from registration provided by Section 4(2) of the Securities Act for these transactions.

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 March 31, 2006 was $174,400, resulting in the issuance of 24,726 shares. There were no stock repurchases in the quarter ended March 31, 2006.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

Financing Arrangement with General Electric Capital Corporation

On May 9, 2006, we entered into an amendment (the "Amendment") of our Master Security Agreement, dated as of December 20, 2002, as amended, with General Electric Capital Corporation (the "GECC Agreement") and the related loan proposal (the "Proposal"), which comprise our capital equipment lease financing facility.

Under the terms of the Amendment, GECC agreed to extend the GECC Agreement and the Proposal, which would have expired April 30, 2006, through October 2006**,** and, subject to the conditions set forth in the Amendment and the GECC Agreement, agreed to make available the entire loan amount provided under the Proposal, a portion of which previously would not have been made available prior to the Company obtaining FDA approval of Surfaxin for the prevention and treatment of RDS in premature infants. Under the Amendment, subject to certain conditions, we will have access to a total of $2.5 million in addition to amounts already outstanding under the GECC Agreement.

Under the Amendment, we have agreed that, except for certain permitted liens, we will not subject our intellectual property to any liens, claims or encumbrances of any kind. For this purpose, “intellectual property” consists of our material owned and licensed patents, trademarks and copyrights used in our research and development activities. In addition, we have agreed to provide GECC a limited security interest in certain proceeds and records related to specified components of our intellectual property.

Under the GECC Agreement, laboratory and manufacturing equipment is financed over 48 months and all other equipment is financed over 36 months, and interest rates vary in accordance with changes in the three and four year treasury rates.

Employment Agreements

On May 4, 2006, the Company entered into amended and restated employment agreements with five of its executive officers, the primary purpose of which was to extent the terms of the agreements beyond December 31, 2006. The amendments are intended to retain and provide incentives to the Company’s senior management.

Employment Agreement with Robert J. Capetola, Ph.D.

Under the amended and restated employment agreement, Dr. Capetola will continue to serve as the Company’s President and Chief Executive Officer for a two-year employment term ending on May 3, 2008. The agreement will automatically renew for consecutive additional one-year terms, unless either party gives 90-days prior notice of termination. Dr. Capetola is currently entitled to an annual base salary of $470,000 and is also eligible for incentive bonus compensation, in cash or equity, as determined by the Compensation Committee. Dr. Capetola is also entitled to reimbursement for leased automobile costs.

If Dr. Capetola’s employment is terminated without Cause or he terminates for Good Reason, as defined in his employment agreement, he will be entitled to severance benefits including: a pro-rata bonus for the year of termination; a severance payment equal to twice his salary and bonus; benefits continuation for two years; and all stock options held by Dr. Capetola shall accelerate and become fully vested and shall remain exercisable for the remainder of their stated terms.

If Dr. Capetola’s employment is terminated without Cause or if Dr. Capetola resigns for Good Reason within 36 months after a change in control, or if Dr. Capetola resigns for any reason in the 30-day period commencing six months after a change in control, he will be entitled to the benefits described above except that his severance payment will be three times his salary and bonus and his benefits will continue for three years.

If there is a change in control, for each fiscal year ending within the following 36-month period, Dr. Capetola will be entitled to a bonus equal to his highest annual bonus during the three years preceding such change in control. In addition, upon any change of control, all outstanding stock options held by him shall accelerate and become fully vested.

If any compensation payable to Dr. Capetola is subject to an excise tax under Section 4999 of the Internal Revenue Code, the Company will make an additional payment to Dr. Capetola equal to the amount of such excise tax, as well as the income tax and excise tax applicable to such payment.

The agreement prohibits Dr. Capetola from competing with the Company throughout his employment term and for a period of 15 months following any termination.

Employment Agreement with Kathryn A. Cole

Under the amended and restated employment agreement, Ms. Cole will continue to serve as the Company's Senior Vice President of Human Resources through December 31, 2007. On each January 1st thereafter, the agreement will automatically renew for an additional one-year term, unless either party gives 90-days prior notice of termination. Ms. Cole is entitled to an annual base salary of at least $180,000 and is also eligible for incentive bonus compensation, in cash or equity, as determined by the Compensation Committee.

Employment Agreement with John G. Cooper

Under the amended and restated employment agreement, Mr. Cooper will continue to serve as the Company's Executive Vice President and Chief Financial Officer through May 3, 2008. On each May 4th thereafter, the agreement will automatically renew for an additional one-year term, unless either party gives 90-days prior notice of termination. Mr. Cooper is entitled to an annual base salary of at least $292,000 and is also eligible for incentive bonus compensation, in cash or equity, as determined by the Compensation Committee.

Employment Agreement with David L. Lopez, Esq., CPA

Under the amended and restated employment agreement, Mr. Lopez will continue to serve as the Company's Executive Vice President and General Counsel through May 3, 2008. On each May 4th thereafter, the agreement will automatically renew for an additional one-year term, unless either party gives 90-days prior notice of termination. Mr. Lopez is entitled to an annual base salary of at least $290,000 and is also eligible for incentive bonus compensation, in cash or equity, as determined by the Compensation Committee. He is also entitled to $7,000 per annum to cover the cost of tuition, fees, books and other materials related to professional courses, and $1,500 per annum to cover fees and costs relating to professional legal and accounting continuing education.

Employment Agreement with Robert Segal, M.D., F.A.C.P.

Under the amended and restated employment agreement, Dr. Segal will continue to serve as the Company's Senior Vice President, Medical and Scientific Affairs and Chief Medical Officer through December 31, 2007. On each January 1st thereafter, the agreement will automatically renew for an additional one-year term, unless either party gives 90-days prior notice of termination. Dr. Segal is entitled to an annual base salary of at least $265,000 and is also eligible for incentive bonus compensation, in cash or equity, as determined by the Compensation Committee.

General Terms of the Employment Agreements of Ms. Cole, Mr. Cooper, Mr. Lopez and Dr. Segal

If the employment of Ms. Cole, Mr. Cooper, Mr. Lopez or Dr. Segal is terminated without Cause or if any of them should terminate their employment for Good Reason, as defined in their respective agreements, such officer will be entitled to severance benefits including a severance payment equal to such officer's then current base salary and bonus, a pro-rata bonus for the year of termination, and benefits continuation for a year. However, if the employment of any of such executive officers is terminated by the Company without Cause or if such officer resigns for Good Reason within 24 months after a change in control, in addition to a pro-rata bonus for the year of termination, each such officer will be entitled to a severance payment equal to two times such officer's then current base salary and bonus, severance benefits continuation for two years, the acceleration and full vesting of all outstanding stock options granted to such officer and the continued exercisability of such options for the remainder of their stated terms.

If there is a change in control, then for each fiscal year ending within the 24-month period following such change in control, each of the foregoing executive officers is entitled to a bonus equal to his or her highest annual bonus during the three years preceding such change in control.

All such officers have agreed not to engage in activities competitive with the Company's business for 12 months (24 months in the case of a termination in connection with a change in control) following termination of employment.

If any compensation payable to any of these officers is subject to an excise tax under Section 4999 of the Internal Revenue Code, the Company will make an additional payment to such officer equal to the amount of such excise tax, as well as the income tax and excise tax applicable to such payment.

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: May 10, 2006

By: /s/ Robert J. Capetola

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

Date: May 10, 2006

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.

Exhibit No.	Description	Method of Filing
3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
3.2	Certificate of Amendment to the Certificate of Incorporation of Discovery, dated as of May 28, 2004.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 9, 2004.
3.3	Certificate of Amendment to the Restated Certificate of Incorporation of Discovery, dated as of July 8, 2005.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, as filed with the SEC on August 8, 2005.
3.4	Amended and Restated By-Laws of Discovery.	Incorporated by reference to Exhibit 3.2 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, as filed with the SEC on March 15, 2004.
3.5	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004.	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6, 2004.
4.1	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 6, 2004.
4.2	Form of Class E Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on March 29, 2000.
4.3	Form of Unit Purchase Option issued to Paramount Capital, Inc.	Incorporated by reference to Exhibit 4.4 to Discovery's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999, as filed with the SEC on March 30, 2000.

48

Exhibit No.	Description	Method of Filing

4.4	Form of Class A Investor Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 20, 2003.
4.5	Class B Investor Warrant, dated July 7, 2004, issued to Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on July 9, 2004.
4.6	Warrant Agreement, dated as of November 3, 2004, by and between Discovery and QFinance, Inc.	Incorporated by reference to Exhibit 4.1 of Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.
4.7	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.8	$8,500,000 Amended and Restated Promissory Note, amended and restated as of November 3, 2004, by and between Discovery and PharmaBio Development Inc.	Incorporated by reference to Exhibit 4.2 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.
4.9	Registration Rights Agreement, dated as of July 7, 2004, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2004.
4.10	Registration Rights Agreement, dated April 17, 2006, by and between Discovery and Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
10.1	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert J. Capetola, Ph.D.	Filed herewith.
10.2	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and John G. Cooper	Filed herewith.

Exhibit No.	Description	Method of Filing
10.3	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and David L. Lopez, Esq., CPA	Filed herewith.
10.4	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Robert Segal, M.D., F.A.C.P.	Filed herewith.
10.5	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Kathryn A. Cole	Filed herewith.
10.6	Amendment No. 2, dated as of September 26, 2003, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Filed herewith.
10.7	Amendment No.3, dated as of December 22, 2004, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Filed herewith.
10.8	Amendment No.4, dated as of May 9, 2006, to the Master Security Agreement between General Electric Capital Corporation and Discovery.	Filed herewith.
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.