

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

**FORM 10-Q**

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

For the quarterly period ended March 31, 2007

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-26422

**DISCOVERY LABORATORIES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**94-3171943**

(I.R.S. Employer  
Identification 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  NO

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  Accelerated filer  Non-accelerated filer

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

As of May 7, 2007, 84,592,550 shares of the registrant's common stock, par value \$0.001 per share, were outstanding.

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Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Discovery Laboratories, Inc., 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 (Exchange Act). The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, our research and development programs and planning for and timing of any clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; implementation of a corrective action and preventive plan to remediate manufacturing issues related to the April 2006 process validation stability failures and, following such remediation, plans with respect to the manufacture and release and stability testing of new process validation batches of Surfaxin®; plans regarding strategic alliances and collaboration arrangements with pharmaceutical companies and others to develop, manufacture and market our drug products; research and development of particular drug products, technologies and aerosolization drug devices; the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations.

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

- the risk that we may not successfully develop and market our products, and even if we do, we may not become profitable;
- risks relating to the progress of our research and development;
- risks relating to significant, time-consuming and costly research and development efforts, including pre-clinical studies, clinical trials and testing, and the risk that clinical trials may be delayed, halted or fail;
- risks relating to the rigorous regulatory approval process required for any products that we may develop independently, with our development partners or in connection with our collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- risks that the FDA or other regulatory authorities may not accept any applications we file;
- risks that the FDA or other regulatory authorities may withhold or delay consideration of any applications that we file or limit such applications to particular indications or apply other label limitations;
- risks that, after acceptance and review of applications that we file, the FDA or other regulatory authorities will not approve the marketing and sale of our drug product candidates;
- risks that we will not timely and successfully resolve the Chemistry, Manufacturing and Controls (CMC) and current Good Manufacturing Practices-related matters at our manufacturing operations in Totowa, NJ with respect to Surfaxin and our other SRTs presently under development, including those identified in connection with our process validation stability failures and matters that were noted by the FDA in its inspectional reports on Form FDA 483;
- risks that the CMC section of our NDA will not satisfy the FDA;
- risks relating to our own drug manufacturing operations and the drug manufacturing operations of our third-party suppliers and contract manufacturers;
- risks relating to the ability of our development partners and third-party suppliers of materials, drug substance and aerosolization systems and related components to provide us with adequate supplies and expertise to support manufacture of drug product for initiation and completion of our clinical studies;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;
- risks relating to our ability and the ability of our collaborators and development partners to develop and successfully manufacture and commercialize products that combine our drug products with innovative aerosolization technologies;
- risks that financial market conditions may change, additional financings could result in equity dilution, or the Company will be unable to maintain the Nasdaq Global Market listing requirements, causing the price of the Company’s shares of common stock to decline;
- the risk that we will not be able to raise additional capital or enter into additional strategic alliances and collaboration arrangements (including strategic alliances in support of our aerosol and other Surfactant Replacement Therapies (SRT));
- the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;
- risks relating to our ability to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all;
- the risk that we or our marketing partners will not succeed in developing market awareness of our products;
- the risk that we or our development partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;
- risks relating to the maintenance, protection and expiry of the patents and licenses related to our SRT and the potential development of competing therapies and/or technologies by other companies;
- risks relating to the impact of securities, product liability, and other litigation or claims that have been and may be brought against the Company and its officers and directors;
- risks relating to reimbursement and health care reform; and
- other risks and uncertainties detailed in “Risk Factors” and in the documents incorporated by reference in this report.

Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

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, 2007 (Unaudited)	December 31, 2006
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 18,079	\$ 26,173
Restricted cash	669	829
Available-for-sale marketable securities	2,000	--
Prepaid expenses and other current assets	216	565
Total Current Assets	20,964	27,567
Property and equipment, net	4,831	4,794
Deferred financing costs and other assets	1,902	2,039
Total Assets	<u>\$ 27,697</u>	<u>\$ 34,400</u>
<b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,119	\$ 5,953
Capitalized leases and note payable, current portion	1,970	2,015
Total Current Liabilities	7,089	7,968
Loan payable, non-current portion, including accrued interest	9,086	8,907
Capitalized leases and note payable, non-current portion	2,238	2,687
Other liabilities	516	516
Total Liabilities	18,929	20,078
Stockholders' Equity:		
Common stock, \$0.001 par value; 180,000 shares authorized; 70,848 and 69,871 shares issued; and 70,535 and 69,558 shares outstanding at March 31, 2007 and December 31, 2006, respectively.	71	70
Additional paid-in capital	268,359	265,604
Accumulated deficit	(256,608)	(248,298)
Treasury stock (at cost); 313 shares at March 31, 2007 and December 31, 2006.	(3,054)	(3,054)
Total Stockholders' Equity	8,768	14,322
Total Liabilities & Stockholders' Equity	<u>\$ 27,697</u>	<u>\$ 34,400</u>

See notes to consolidated financial statements

**DISCOVERY LABORATORIES, INC. AND SUBSIDIARY**  
**Consolidated Statements of Operations**  
(Unaudited)  
*(in thousands, except per share data)*

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<u>2007</u>	<u>2006</u>
Revenue	\$ --	\$ --
Expenses:		
Research and development	5,422	7,613
General and administrative	2,754	8,682
Total expenses	<u>8,176</u>	<u>16,295</u>
Operating loss	(8,176)	(16,295)
Other income / (expense):		
Interest and other income	306	800
Interest expense	<u>(440)</u>	<u>(300)</u>
Other income / (expense), net	(134)	500
Net loss	<u>\$ (8,310)</u>	<u>\$ (15,795)</u>
Net loss per common share -		
Basic and diluted	\$ (0.12)	\$ (0.26)
Weighted average number of common shares outstanding - basic and diluted	69,989	61,170

*See notes to consolidated financial statements*

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,310)	\$ (15,795)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	376	215
Stock-based compensation and 401(k) match	751	2,077
<b>Changes in:</b>		
Prepaid expenses and other assets	348	(316)
Accounts payable and accrued expenses	(834)	628
Other liabilities	179	--
Net cash used in operating activities	<u>(7,490)</u>	<u>(13,191)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(275)	(691)
Restricted cash	160	(33)
Purchases of marketable securities	(2,000)	(4,631)
Proceeds from sales or maturity of marketable securities	--	3,219
Net cash used in investing activities	<u>(2,115)</u>	<u>(2,136)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of securities, net of expenses	2,005	728
Equipment financed through capital lease obligation	--	171
Principal payments under capital lease obligation	(494)	(356)
Net cash provided by financing activities	<u>1,511</u>	<u>543</u>
Net decrease in cash and cash equivalents	(8,094)	(14,784)
Cash and cash equivalents - beginning of period	26,173	47,010
Cash and cash equivalents - end of period	<u>\$ 18,079</u>	<u>\$ 32,226</u>
<b>Supplementary disclosure of cash flows information:</b>		
Interest paid	\$ 123	\$ 296

*See notes to consolidated financial statements*

## **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 and diseases. 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, to treat conditions for which 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 filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for its lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In April 2006, the Company received an Approvable Letter from the FDA in connection with this NDA. The Company is also developing Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants. Aerosurf™ is the Company's proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP) and is being developed for the prevention and treatment of infants at risk for respiratory failure. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation.

In addition to potentially treating respiratory conditions prevalent in the NICU, the Company believes that its SRT will also potentially address a variety of debilitating respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, such as Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), Acute Respiratory Failure (ARF), chronic obstructive pulmonary disorder (COPD), cystic fibrosis, asthma and other debilitating respiratory conditions.

The Company has implemented a business strategy that includes: (i) taking actions intended to gain regulatory approvals for Surfaxin for the prevention of RDS in premature infants in the United States; (ii) continued investment in development of SRT pipeline programs, including Surfaxin for neonatal and pediatric conditions and Aerosurf, which uses the aerosol-generating technology rights that the Company has licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis); (iii) continued investment in enhancements to the Company's quality systems and manufacturing capabilities, including its operations in Totowa, NJ (which the Company acquired in December 2005), to produce surfactant drug products to meet the anticipated pre-clinical, clinical and potential future commercial requirements of Surfaxin and the Company's other SRT product candidates, beginning with Aerosurf, and potentially to develop new and enhanced formulations of Surfaxin and our other SRT product candidates. The Company's long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities for the production of its precision-engineered SRT drug products; and (iv) seeking investments of additional capital and potentially entering into collaboration agreements and 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, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. Certain prior period balances have been reclassified to conform to the current period presentation. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2006.



## **Note 2 - Accounting Principles and Recent Accounting Pronouncements**

### *Accounting Principles*

There have been no changes to the Company's critical accounting policies since December 31, 2006. For more information on critical accounting policies, refer to the Annual Report on Form 10-K for the year ended December 31, 2006. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

### *Recent Accounting Pronouncements*

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, ("FIN 48"). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on the condensed consolidated financial statements.

## **Note 3 - 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 4 - Comprehensive Loss**

Total comprehensive loss was \$8.3 million for the three months ended March 31, 2007, and \$15.8 million for the three months ended March 31, 2006. 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 the Company discloses such amounts separately on the Company's balance sheets. The primary component of Restricted Cash is a cash security deposit in the amount of \$600,000 securing a letter of credit in the same amount related to the Company's lease agreement dated May 26, 2004 for office space in Warrington, Pennsylvania. Beginning in March 2010, the security deposit and the letter of credit related to the lease agreement 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 February 2013, the letter of credit will expire.

## **Note 6 - Stock-Based Employee Compensation**

The Company has a stock-based employee compensation plan that is intended to attract, retain and provide incentives for employees, officers and directors, and to align stockholder and employee interests. The Company uses the Black-Scholes option pricing model to determine the fair value of stock options and amortizes the stock-based compensation expense over the requisite service periods of the stock options. The fair value of the stock options is determined on the date of grant using the Black-Scholes option-pricing model. The fair value of stock options is affected by the Company's stock price and several subjective variables, including the expected stock price volatility over the term of the option, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends.

The Company uses historical data and other factors to estimate the expected term, volatility and forfeiture rates within the valuation model. The risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant. The Company has not and does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model. The Company estimates forfeitures of unvested stock options at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates, resulting in recognition of stock-based compensation expense only for those options that vest.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing formula and the assumptions noted in the following table:

	March 31, 2007	March 31, 2006
Expected volatility	95%	81%
Expected term	4 & 5 years	5 years
Risk-free rate	4.6%	4.4%
Expected dividends	--	--

The total stock-based employee compensation for the three months ended March 31, 2007 and 2006 was \$0.6 million and \$1.7 million, respectively. As of March 31, 2007, there was \$6.4 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average vesting period of 1.95 years.

#### **Note 7 - Working Capital**

Cash is required to fund the Company's working capital needs, to purchase capital assets, and to pay debt service, including principal and interest payments. The Company does not currently have any source of operating revenue and will require significant amounts of cash to continue to fund operations, clinical trials and research and development efforts until such time, if ever, that one of the Company's products receives regulatory approval for marketing and begins to generate sales. Since the Company has not generated any revenue from the sale of any products, the Company has primarily relied upon the capital markets and debt financings as its primary sources of funding. The Company will continue to be opportunistic in accessing the capital markets to obtain financing on terms satisfactory to the Company. The Company plans to fund its 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;
- sales of the Company's other product candidates, if approved;
- capital lease financings; and
- interest earned on invested capital.

After taking into account the registered direct public offering in April 2007, resulting in gross proceeds of \$30.2 million, and before taking into account any strategic alternatives, other potential financings or amounts that may be potentially available through the new Committed Equity Financing Facility (CEFF) entered into with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in April 2006 (discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources"), the Company believes that its current working capital is sufficient to meet planned activities into 2008. Use of the CEFF is subject to certain conditions, including a limitation on the total number of shares of common stock that may be issued by the Company under the CEFF (approximately 7.1 million shares were available for issuance under the CEFF as of March 31, 2007). In addition, during the eight trading day pricing period for a draw down, if the volume weighted average price of the Company's common stock (VWAP) for any one trading day is less than the greater of (i) \$2.00 or (ii) 85 percent of the closing price of the Company's 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 that the Company had initially specified. The Company anticipates using the CEFF, when available, to support working capital needs in 2007.

## **Note 8 - Q2 2006 Restructuring Charge**

In April 2006, the Company received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants and announced that ongoing analysis of data from Surfaxin process validation batches that the Company had manufactured as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. As a result, in April 2006, the Company reduced its staff levels and reorganized corporate management to lower the its cost structure and re-align its operations with changed business priorities. The Company incurred a restructuring charge of \$4.8 million in the second quarter of 2006 associated with staff reductions and the close-out of certain commercial programs, which was accounted for in accordance with Statement No. 146 "*Accounting for Costs Associated with Exit or Disposal Activities*".

As of March 31, 2007, payments totaling \$4.0 million had been made related to these items and \$0.8 million was unpaid. Of the \$0.8 million that was unpaid as of March 31, 2007, \$0.6 million was included in accounts payable and accrued expenses and \$0.2 million was classified as a long-term liability.

## **Note 9 -Litigation**

On March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased the Company's publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various public statements made by the Company. The amended complaint had been filed on November 30, 2006 against the Company, its Chief Executive Officer, Robert J. Capetola, and its former Chief Operating Officer, Christopher J. Schaber, under the caption "In re: Discovery Laboratories Securities Litigation" and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs 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. On April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania.

On May 1, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the consolidated shareholder derivative complaint that was filed on December 29, 2006 under the caption "In re: Discovery Laboratories Derivative Litigation." The complaint named as defendants the Company's Chief Executive Officer, Robert J. Capetola, and Herbert H. McDade, Jr., Antonio Esteve, Max E. Link, Marvin E. Rosenthale, W. Thomas Amick, all directors of the Company, and Christopher J. Schaber, the Company's former Chief Operating Officer and sought an award of damages, disgorgement of profits, injunctive and other equitable relief and award of attorneys' fees and costs. The plaintiffs were granted leave to file a second amended complaint by May 15, 2007.

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

The Company has from time to time been involved in disputes arising in the ordinary course of business, including in connection with the termination of its commercial programs (discussed in Note 11 - 2006 Restructuring Charge). Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. While it is impossible to predict with certainty the eventual outcome of such claims, the Company believes they are unlikely to have a material adverse effect on its financial condition or results of operations. However, there can be no assurance that the Company will be successful in any proceeding to which it may be a party.

## Note 10 - Subsequent Events

On April 5, 2007, the Company completed a registered direct offering to institutional investors resulting in gross proceeds of \$30.2 million (\$28.2 million net) from the issuance of 14,050,000 shares of common stock at \$2.15 per share.

## 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 Surfactant Replacement Therapies (SRT) for respiratory disorders and 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 SRT 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), Pediatric Intensive Care Unit (PICU), critical care unit and other hospital settings, where there are few or no approved therapies available.

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU. We have filed a NDA with the FDA for our lead product, Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In April 2006, we received an Approvable Letter from the FDA in connection with this NDA. We are also developing Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants, a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. Aerosurf™ is our proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP) and is being developed for the prevention and treatment of infants at risk for respiratory failure. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation.

In addition to potentially treating respiratory conditions prevalent in the NICU, we also believe that our SRT potentially will address a variety of debilitating respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, such as Acute Respiratory Failure (ARF), cystic fibrosis, Acute Lung Injury (ALI), Acute Respiratory Distress Syndrome (ARDS), chronic obstructive pulmonary disorder (COPD), asthma and other debilitating respiratory conditions.

We have implemented a business strategy that includes:

- taking actions intended to gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States, including (i) finalizing and submitting our response to the April 2006 Approvable Letter, which focused on the Chemistry, Manufacturing and Controls (CMC) portion of our NDA; and (ii) completing analysis and remediation of manufacturing issues related to the April 2006 process validation stability failure;
- continued investment in the development of our SRT pipeline programs, including Surfaxin for neonatal and pediatric conditions and Aerosurf, which uses the aerosol-generating technology rights that we have licensed through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc. (Chrysalis);

- continued investment in enhancements to our quality systems and our manufacturing capabilities, including our operations in Totowa, NJ (which we acquired in December 2005). We plan to (i) produce surfactant drug products to meet the anticipated pre-clinical, clinical and potential future commercial needs of Surfaxin and our other SRT product candidates, beginning with Aerosurf, and (ii) potentially develop new and enhanced formulations of Surfaxin and our other SRT product candidates. We view the acquisition of our own manufacturing operation as an initial step in our long-term manufacturing strategy. Our long-term strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered SRT drug products; and
- seeking investments of additional capital and potentially entering into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. We continue to evaluate a variety of strategic transactions intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

Since our inception, we have incurred significant losses and, as of March 31, 2007, we had an accumulated deficit of \$256.6 million (including historical results of predecessor companies). The majority of our expenditures to date have been for and in support of research and development activities. 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, 2007, we had: (i) cash of \$20.7 million; (ii) approximately 7.1 million shares potentially available for issuance under the CEFF with Kingsbridge for future financings (not to exceed \$40.5 million), subject to the terms and conditions of the agreement; (iii) \$9.1 million outstanding (\$8.5 million principal and \$0.6 million of accrued interest as of March 31, 2007) on a loan from PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), the strategic investment group of Quintiles Transnational Corp. (Quintiles), which is due and payable together with all accrued interest on April 30, 2010; and (iv) \$4.2 million outstanding on a capital equipment lease financing arrangement with General Electric Capital Corporation (GECC), which expired on October 31, 2006, of which an aggregate of \$7.9 million was drawn during the life of the facility. 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, 2007 and 2006 were \$5.4 million and \$7.6 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, formulation development, manufacturing development, clinical and regulatory operations and other direct preclinical and clinical projects.

These cost categories typically include the following expenses:

### 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: (1) costs associated with operating our manufacturing facility in Totowa, NJ (which we acquired from our then-contract manufacturer, Laureate Pharma, Inc. (Laureate) in December 2005) to support the production of clinical and anticipated commercial drug supply for the Company’s SRT programs, such as employee expenses, depreciation, the purchase of drug substances, quality control and assurance activities, and analytical services; (2) continued investment in our quality assurance and analytical chemistry capabilities, including implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process and expanding the operations to meet production needs for our SRT pipeline in accordance with cGMP; and (3) expenses associated with our ongoing comprehensive investigation of the April 2006 Surfaxin process validation stability failure and remediation of the Company’s related manufacturing issues and activities associated with developing data and other information necessary for our formal response to the Surfaxin Approvable Letter.

## Unallocated Development - Clinical, Regulatory and Formulation Development Operations

Clinical, regulatory and formulation development operations reflect the preparation, implementation and management of our clinical trial activities in accordance with current good clinical practices (cGCPs) and research and development of aerosolized and other related formulations of our precision-engineered lung surfactant, engineering of aerosol delivery systems and analytical chemistry activities to support the continued development of Surfaxin. Included in unallocated clinical, regulatory and formulation development 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, including such activities associated with developing data and other information necessary for our formal response to the Surfaxin Approvable Letter.

## Direct Pre-Clinical and Clinical Program Expenses

Direct pre-clinical and clinical program expenses include pre-clinical activities associated with the development of SRT formulations prior to the initiation of any potential human clinical trials and activities associated with conducting clinical trials, including 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 each of the foregoing categories for the three months ended March 31, 2007 and 2006:

(Dollars in thousands)

	Period Ended March 31,	
	2007	2006
<b>Research and Development Expenses:</b>		
Manufacturing development	\$ 2,336	\$ 2,507
Unallocated development - clinical and regulatory operations	2,029	3,030
Direct pre-clinical and clinical program expenses	1,057	2,076
<b>Total Research and Development Expenses</b>	<b>\$ 5,422</b>	<b>\$ 7,613</b>

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. The status and anticipated completion date of each of our lead SRT programs are discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Plan of Operations." 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 "Risk Factors" section herein and those contained in our most recent Annual Report on Form 10-K.

Development risk factors include, but are not limited to:

- Completion of pre-clinical and clinical trials of our SRT product candidates with scientific results that are sufficient to support further development and/or regulatory approval;
- Receipt of necessary regulatory approvals;
- Obtaining adequate supplies of surfactant active drug substances on commercially reasonable terms;
- Obtaining capital necessary to fund our operations, including our research and development efforts, manufacturing requirements and clinical trials;
- Performance of our third-party collaborators and suppliers on whom we rely for supply of drug substances, medical device components and related services necessary to manufacture our SRT drug product candidates, including Surfaxin and Aerosurf;
- Timely and successful resolution of the Chemistry, Manufacturing and Controls (CMC) and cGMP-related matters at our manufacturing operations in Totowa, NJ with respect to Surfaxin and our other SRTs presently under development, including those we have identified in connection with our recent process validation stability failures and matters that were noted by the FDA in its inspectional reports on Form FDA 483;
- Successful manufacture of SRT drug product candidates, including Surfaxin, at our operations in New Jersey;
- Successful development and implementation of a manufacturing strategy for the Chrysalis aerosolization device and related materials to support clinical studies and commercialization of Aerosurf; and
- Obtaining additional manufacturing operations, for which we presently have limited resources.

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

- Slow patient enrollment;
- Long treatment time required to demonstrate effectiveness;
- Lack of sufficient clinical supplies and material;
- Adverse medical events or side effects in treated patients;
- Lack of compatibility with 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 and generate revenues from the sale of our products, such a failure would have a material adverse effect on our value, financial condition and results of operations.

## **CORPORATE PARTNERSHIP AGREEMENTS**

### **Chrysalis Technologies, a Division of Philip Morris USA Inc.**

In December 2005, we entered into a strategic alliance with Chrysalis to develop and commercialize aerosol SRT to address a broad range of serious respiratory conditions, such as neonatal respiratory failure, ALI, cystic fibrosis, chronic obstructive respiratory disorder (COPD), asthma, and others. Through this alliance, we gained exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases. The alliance unites two complementary respiratory technologies - our precision-engineered surfactant technology with Chrysalis' novel aerosolization technology that is being developed to deliver 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 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 our respective capabilities and resources to support and fund the design and development of combination 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 aerosolization device platform, disposable dose packets and patient interface. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the combination 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, an aerosolized formulation administered via nCPAP to treat premature infants in the NICU at risk for RDS. We are also planning an adult program utilizing the Chrysalis aerosolization technology to develop aerosolized SRT administered as a prophylactic for patients in the hospital at risk for ALI and will be assessing the timing for implementation of our adult program in 2007.

#### **Laboratorios del Dr. Esteve, S.A.**

In December 2004, we further restructured our strategic alliance with Laboratorios del Dr. Esteve, S.A. (Esteve) for the development, marketing and sales of our products. We had first entered into the alliance in 1999 and had revised it in 2002 to broaden the territory to include all of Europe, Central and South America, and Mexico. Under the 2004 revision, we regained full commercialization rights to our SRT, including Surfaxin for the prevention of RDS in premature infants and the treatment of ARDS in adults, in key European markets, Central America and South America. 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. We also agreed to pay to Esteve 10% of cash up-front and milestone fees (not to exceed \$20 million in the aggregate) that we may receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain other SRTs in the territory for which we had previously granted a license to Esteve. 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 Dompé farmaceutici s.p.a. (Dompé), a privately owned Italian company. Under the sublicense agreement, Dompé will be responsible for sales, marketing and distribution of Surfaxin in Italy.

#### **PLAN OF OPERATIONS**

We have incurred substantial losses since inception and expect to continue to expend substantial amounts for continued product research, development, manufacturing, and general business activities. We will need to generate significant revenues from product sales, related royalties and transfer prices to achieve and maintain profitability.

Through March 31, 2007, 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 collaboration and other 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, 2007, we had not generated taxable income. At December 31, 2006, net operating losses available to offset future taxable income for Federal tax purposes were approximately \$229.8 million. The future utilization of such loss carryforward may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we had a research and development tax credit carryforward of \$5.2 million at December 31, 2006. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 through 2026.



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. See “Management’s Discussion and Analysis - Research and Development.”

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.

#### *Surfaxin for the Prevention of RDS in Premature Infants*

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 information primarily focused on the chemistry, manufacturing and controls (CMC) section of the NDA, predominately involving the further tightening of active ingredient and drug product specifications and related controls. Also in April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our contract manufacturer, Laureate Pharma, Inc. (Laureate) as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately initiated a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to determine the cause of the failure. As a result of this investigation, we developed a corrective action and preventative action plan to remediate the related manufacturing issues.

In September 2006, we submitted a request for a meeting with the FDA together with an information package that covered certain of the key CMC matters contained in the Approvable Letter and provided information concerning the status and interim findings of our comprehensive investigation into the Surfaxin process validation stability failure and our efforts to remediate the related manufacturing issues. On December 21, 2006, we attended a meeting with the FDA, the purpose of which was to clarify the issues identified by the FDA in the Approvable Letter and obtain guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin for the prevention of RDS in premature infants. Following that meeting and consistent with the guidance from the FDA, we completed the manufacture of new Surfaxin process validation batches. These process validation batches will undergo continuing stability testing and this stability data is expected to support our formal response to the Approvable Letter, which we presently anticipate filing in September or October 2007. Assuming that the FDA accepts our response as a complete response, we anticipate a six-month FDA review period for potential approval of our NDA for Surfaxin for the prevention of RDS in premature infants.

In June 2006, we voluntarily withdrew the Marketing Authorization Application (MAA) filed in October 2004 with the European Medicines Agency (EMA) for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe because our manufacturing issues would not be resolved within the regulatory time frames mandated by the EMA procedure. Our withdrawal of the MAA precluded final resolution of certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials, which had been the focus of a recent EMA clinical expert meeting and were expected to be reviewed at a planned Oral Explanation before the Committee for Medicinal Products for Human Use (CHMP) in late June 2006. We plan in the future to have further discussions with the EMA and develop a strategy to potentially gain approval for Surfaxin in Europe.

## *Surfaxin for BPD in Premature Infants*

In October 2006, we announced preliminary results of our recently completed Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD. We believe that these results suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD and anticipate determining the next development steps for this program in late 2007 or early 2008.

### *Aerosurf, Aerosolized SRT*

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 (Aeroneb Pro<sup>®</sup>) 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.

We are presently collaborating with Chrysalis on the development of a prototype aerosolization system to deliver Aerosurf to patients in the NICU and, if successful, plan to initiate multiple Phase 2 clinical studies of Aerosurf utilizing the Chrysalis aerosolization technology in the second half of 2007. See “*Surfaxin for the Prevention of RDS in Premature Infants,*” above.

### SRT for Critical Care and Hospital Indications

We are also evaluating the potential development of our proprietary precision-engineered SRT to address respiratory disorders such as ARF, cystic fibrosis, ALI, chronic obstructive respiratory disorder (COPD), asthma, and other debilitating respiratory conditions. We plan on initiating clinical studies in 2007 for certain of these respiratory disorders.

## **Manufacturing**

Our precision-engineered surfactant product candidates, including Surfaxin, must be manufactured in compliance with cGMPs established by the FDA and other international regulatory authorities. Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. It must be aseptically manufactured at our facility as a sterile, liquid suspension and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients.

We plan to 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 - New Jersey Operations

In December 2005, we purchased our manufacturing operations from Laureate (our contract manufacturer at that time) and entered into a transitional services arrangement under which Laureate agreed to provide us with certain limited manufacturing-related support services through December 2006. In July 2006, we completed the transition and terminated the arrangement with Laureate.

Owning the Totowa operation has provided us with direct operational control and, we believe, potentially improved economics for the production of clinical and potential commercial supply of our lead product, Surfaxin, and our SRT pipeline products. This facility is the only facility in which we produce our drug product. We view our acquisition of the Totowa operations as an initial step of our long-term manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf.

In April 2006, ongoing analysis of Surfaxin process validation batches that had been manufactured for us in 2005 by our then contract manufacturer, Laureate, as a requirement for our NDA indicated that certain stability parameters no longer met acceptance criteria. We immediately initiated a comprehensive investigation, which focused on analysis of manufacturing processes, analytical methods and method validation and active pharmaceutical ingredient suppliers, to determine the cause of the failure. As a result of this investigation, we developed a corrective action and preventative action plan to remediate the related manufacturing issues.

In September 2006, we submitted a request for a meeting with the FDA together with an information package that covered certain of the key CMC matters contained in the Approvable Letter and provided information concerning the status and interim findings of our comprehensive investigation into the Surfaxin process validation stability failure and our efforts to remediate the related manufacturing issues. Following a meeting with the FDA on December 21, 2006, and consistent with the guidance from the FDA, we completed the manufacture of new Surfaxin process validation batches, which are undergoing release and ongoing stability testing.

#### Long-Term Manufacturing Capabilities

We are planning to have manufacturing capabilities, primarily through our manufacturing operation in Totowa, NJ, that should allow for sufficient commercial production of Surfaxin, if approved, to supply the potential worldwide demand for the prevention of RDS in premature infants, the prevention and treatment of BPD and all of our anticipated clinical-scale production requirements for SRT for Aerosurf.

We view our acquisition of manufacturing operations in Totowa, NJ as an initial step of our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, potential new formulations and formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. The lease for our Totowa, NJ facility extends through December 2014. In addition to customary lease 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. Taking into account this early termination option, which may cause us to move out of our Totowa, NJ facility as early as December 2009, our long-term manufacturing strategy includes potentially building or acquiring additional manufacturing capabilities, as well as using contract manufacturers, for the production of our precision-engineered SRT drug products.

#### Aerosol Devices and Related Componentry

To manufacture aerosolization systems for our planned clinical trials, we expect to utilize third-party contract manufacturers, suppliers and assemblers. The manufacturing process will require assembly of the key device sub-components that comprise the aerosolization systems, including the aerosol-generating device, the disposable dose delivery packet and patient interface system necessary to administer our aerosolized SRT in patients in the NICU and ICU. We expect that third-party vendors will manufacture these key device sub-components, and ship them to one central location for assembly and integration into the aerosolization system. Once assembled, critical/product contact components and/or assemblies are packaged and sterilized. Each of the aerosolization systems will be quality-control tested prior to release for use in our clinical trials or, potentially, for commercial use. To complete the combination drug-device product, we plan to manufacture the SRT drug product at our Totowa, NJ facility.

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 in the near term 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.

### **Potential Collaboration Agreements and Strategic Partnerships**

We intend to seek investments of additional capital and potentially enter into collaboration agreements and strategic partnerships for the development and commercialization of our SRT product candidates. To assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value, we have engaged Jefferies & Company, Inc. (Jefferies), a New York-based investment banking firm. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

### **CRITICAL ACCOUNTING POLICIES**

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We have identified below our most critical accounting policy.

#### *Research and Development Costs*

Research and development costs are expensed as incurred. We will continue to incur research and development costs as we continue to expand our product development activities. Our research and development costs have included, and will continue to include, expenses for internal development personnel, supplies and facilities, clinical trials, regulatory compliance and reviews, validation of processes and start up costs to establish commercial manufacturing capabilities. Once a product candidate is approved by the FDA, if at all, and we begin commercial manufacturing, we will no longer expense certain manufacturing costs as research and development costs for any such product.

For more information on our other critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2006. There have been no changes to these policies since December 31, 2006. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

### **RESULTS OF OPERATIONS**

The net loss for the three months ended March 31, 2007 and 2006 were \$8.3 million (or \$0.12 per share) and \$15.8 million (or \$0.26 per share), respectively.

#### **Revenue**

The Company did not earn revenue during the three months ended March 31, 2007 or 2006.

## Research and Development Expenses

Research and development expenses for the three months ended March 31, 2007 and 2006 were \$5.4 million and \$7.6 million, respectively. For a description of expenses and research and development activities, see "Management's Discussion and Analysis - Research and Development." For a description of the clinical programs included in research and development, see "Management's Discussion and Analysis - Plan of Operations."

Research and development expenses for the three months ended March 31, 2007 compared to the same period in 2006 primarily reflects:

- (i) Manufacturing development activities (included in research and development expenses) to support the production of clinical and commercial drug supply for our SRT programs, including Surfaxin, in conformance with cGMPs. For the three months ended March 31, 2007 and 2006, manufacturing development expenses were \$2.3 million and \$2.5 million, respectively. Manufacturing development expenses for the three months ended March 31, 2007 primarily consist of (i) costs associated with operating our manufacturing facility to support the production of clinical and anticipated commercial drug supply for our SRT programs; (ii) continued investment in our quality assurance and analytical chemistry capabilities to ensure compliance with current good manufacturing practices (cGMP); (iii) activities associated with developing data and other information necessary for our formal response to the Surfaxin Approvable Letter; and (iv) activities to develop improved formulations of our SRT. The decrease in the first quarter of 2007, compared to the same quarter last year, primarily reflects cost incurred in 2006 for: (i) the initial ownership and operating costs of our manufacturing operations in Totowa, NJ, which we acquired on December 31, 2005; and (ii) certain manufacturing-related support services provided by our previous contract manufacturer that were required during the initial transition period following our acquisition of the manufacturing operations in Totowa, NJ; and
- (ii) Research and development activities, excluding manufacturing development activities, related to the advancement of our SRT pipeline. For the three months ended March 31, 2007 and 2006, expenses related to research and development activities were \$3.1 million and \$5.1 million, respectively. Research and development expenses for the three months ended March 31, 2007 primarily include: (i) costs associated with developing data and other information necessary for our formal response to the Surfaxin Approvable Letter; (ii) development activities related to Aerosurf™, our proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP), to address premature infants at risk for respiratory failure; and (iii) activities to develop Surfaxin and aerosol SRT to address pediatric and adult patients with respiratory disorders. The decrease in the first quarter of 2007, compared to the same quarter last year, primarily reflects cost incurred in 2006 for: (i) clinical activities associated with the Phase 2 clinical trials for BPD in premature infants and ARDS in adults; and (ii) personnel and related costs that were reduced in connection with reorganized corporate management that occurred immediately after the April 2006 Surfaxin process validation stability failure.

## General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2007 and 2006 were \$2.8 million and \$8.7 million, respectively. The decrease is primarily due to costs incurred in 2006 in anticipation of the potential approval and commercial launch of Surfaxin for the prevention of RDS in premature infants. After the April 2006 Surfaxin process validation stability failure, we took immediate steps to lower our costs and suspended pre-launch commercial activities, reduced personnel and reorganized corporate management. General and administrative costs for the three months ended March 31, 2007, primarily include costs associated with executive management, the defense of the securities class action and derivative proceedings (see "Management's Discussion and Analysis - Legal Proceedings"), evaluation of various strategic business alternatives, financial and legal management and other administrative costs.

## Other Income and (Expense)

Other income and (expense) for the three months ended March 31, 2007 and 2006 were \$(0.1) million and \$0.5 million, respectively.

Interest and other income for the three months ended March 31, 2007 and 2006 was \$0.3 million and \$0.8 million, respectively. The decrease is primarily due to: (i) proceeds of \$0.3 million in the first quarter of 2006 from the sale of our Commonwealth of Pennsylvania research and development tax credits; and (ii) a decrease in our average outstanding cash balance for the three months ended March 31, 2007 compared to the same period in 2006; partially offset by (iii) a general increase in earned market interest rates.

Interest, amortization and other expenses for the three months ended March 31, 2007 and 2006 was \$0.4 million and \$0.3 million, respectively. The increase is primarily due to interest expense related to the amortization of deferred financing costs associated with warrants issued to PharmaBio in October 2006 in consideration for renegotiating the terms on the existing \$8.5 million loan. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources."

## LIQUIDITY AND CAPITAL RESOURCES

### Working Capital

We have incurred substantial losses since inception and expect to continue to make significant investments for continued product research, development, manufacturing and commercialization activities. Historically, we have funded our operations primarily through the issuance of equity securities and the use of debt and capital lease facilities.

We are subject to risks customarily associated with the biotechnology industry, which requires significant investment for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable.

We plan to fund our research, development, manufacturing and potential commercialization activities 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;
- sales of our other product candidates, if approved;
- capital lease financings; and
- interest earned on invested capital.

Our capital requirements will depend on many factors, including the success of the product development and commercialization plan. Even if we succeed in developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability. There is no assurance that we will be able to obtain additional capital when needed with acceptable terms, if at all.

We have engaged Jefferies to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. In November 2006, we raised \$10 million in a private placement transaction and, in April 2007, we raised \$30.2 million (\$28.2 million net) in a registered direct offering. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

We have a CEFF that allows us to raise capital, subject to certain conditions, at the time and in amounts deemed suitable to us, during a three-year period ending on May 12, 2009. Use of the CEFF is subject to certain conditions (discussed at "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Committed Equity Financing Facility", below), including a limitation on the total number of shares of common stock that we may issue under the CEFF (approximately 7.1 million shares were available for issuance under the CEFF as of March 31, 2007). We anticipate using the CEFF, when available, to support working capital needs in 2007.

## Cash, Cash Equivalents and Marketable Securities

As of March 31, 2007, we had cash, cash equivalents, restricted cash and marketable securities of \$20.7 million, as compared to \$27.0 million as of December 31, 2006. The decrease is primarily due to: (i) \$7.8 million used in operating activities and purchases of capital expenditures; and (ii) \$0.5 million used to pay principal payments on capital lease arrangements; partially offset by (iii) proceeds of \$2.0 million from a financing pursuant to the CEFF.

On April 5, 2007, we completed a registered direct offering to institutional investors resulting in gross proceeds of \$30.2 million (\$28.2 million net) from the issuance of 14,050,000 shares of common stock at \$2.15 per share.

## Committed Equity Financing Facility

In April 2006, we entered into a new Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, in 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. Our previous Committed Equity Financing Facility, which was with Kingsbridge, entered in July 2004 (2004 CEFF) and under which up to \$47.6 million remained available, automatically terminated on May 12, 2006, the date on which the SEC declared effective the registration statement filed in connection with the CEFF.

The 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 that began on May 12, 2006. We are not obligated to utilize the entire \$50 million available under this CEFF.

The purchase price of shares sold to Kingsbridge under the CEFF is 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 initiation of a “draw down” under the CEFF. The discount on each of these eight trading days is determined as follows:

<b>VWAP*</b>	<b>% of VWAP (Applicable Discount)</b>	
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.

If on any trading day during the eight trading day pricing period for a draw down, the VWAP is less than the greater of (i) \$2.00 or (ii) 85 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period, no shares will be issued with respect to that trading day and the total amount of the draw down 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 our 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. In addition, Kingsbridge may terminate the CEFF under certain circumstances, including if a material adverse effect relating to our business continues for 10 trading days after notice of the material adverse effect.

In 2006, in connection with the CEFF, we issued a Class C Investor Warrant to Kingsbridge to purchase up to 490,000 shares of our 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 is exercisable for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$2.8 million.

In May 2006, we completed a financing pursuant to the CEFF resulting in proceeds of \$2.2 million from the issuance of 1,078,519 shares of our common stock at an average price per share, after the applicable discount, of \$2.03.

In October 2006, we completed a financing pursuant to the CEFF resulting in proceeds of \$2.3 million from the issuance of 1,204,867 shares of our common stock at an average price per share, after the applicable discount, of \$1.91.

In November 2006, we completed a financing pursuant to the CEFF resulting in proceeds of \$3 million from the issuance of 1,371,516 shares of our common stock at an average price per share, after the applicable discount, of approximately \$2.19.

In February 2007, we completed a financing pursuant to the CEFF resulting in proceeds of \$2 million from the issuance of 942,949 shares of our common stock at an average price per share, after the applicable discount, of \$2.12.

As of March 31, 2007, there were approximately 7.1 million shares available for issuance under the CEFF (up to a maximum of \$40.5 million in gross proceeds) for future financings.

In 2004, in connection with the 2004 CEFF, we issued a Class B Investor warrant to Kingsbridge to purchase up to 375,000 shares of our common stock at an exercise price equal to \$12.0744 per share. The warrant, which expires in January 2010, is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds, if exercised, of approximately \$4.5 million. As of December 31, 2006, the Class B Investor Warrant had not been exercised.

#### **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 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 million. In April 2007, we completed a registered direct offering of 14,050,000 shares of our common stock to select institutional investors resulting in gross proceeds of \$30.2 million.

The universal shelf registration statement may permit us, from time to time, to offer and sell up to an additional approximately \$49.8 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**

##### *Loan with PharmaBio*

PharmaBio, the strategic investment group of Quintiles, extended to us a secured, revolving credit facility of \$8.5 to \$10 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States. Interest was payable quarterly in arrears at an annual rate equal to the greater of 8% or the prime rate plus 2%. As part of a renegotiation in 2004, the maturity date was extended from December 10, 2004 to December 31, 2006. The interest remained unchanged. In October 2006, we restructured the existing \$8.5 million loan with PharmaBio and, as a result, the maturity date of the loan has been further extended by 40 months from December 31, 2006 to April 30, 2010.

Beginning on October 1, 2006, interest on the loan will accrue at the prime rate, compounded annually. All unpaid interest, including interest payable with respect to the quarter ending September 30, 2006, will now be payable on April 30, 2010, the maturity date of the loan. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium.



In connection with the restructuring, in October 2006, we and PharmaBio amended and restated the existing loan documents. In addition, our obligations to PharmaBio under the loan documents are now secured by an interest in substantially all of our assets, subject to limited exceptions set forth in the Security Agreement (the PharmaBio Collateral).

Also in October 2006, in consideration of PharmaBio's agreement to restructure the loan, we entered into a Warrant Agreement with PharmaBio, pursuant to which PharmaBio has the right to purchase 1.5 million shares of our common stock at an exercise price equal to \$3.5813 per share. The warrants have a seven-year term and are exercisable, in whole or in part, for cash, cancellation of a portion of our indebtedness under the Loan Agreement, or a combination of the foregoing, in an amount equal to the aggregate purchase price for the shares being purchased upon any exercise. Under the Warrant Agreement, we filed a registration statement with the SEC with respect to the resale of the shares issuable upon exercise of the warrants.

As of March 31, 2007, the outstanding balance under the loan was \$9.1 million (\$8.5 million of pre-restructured principal and \$0.6 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

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

Our capital lease financing arrangements have been primarily with the Life Science and Technology Finance Division of General Electric Capital Corporation (GECC) pursuant to a Master Security Agreement dated December 20, 2002 (Master Security Agreement).

Under the Master Security Agreement, we purchased capital equipment, including manufacturing, information technology systems, laboratory, office and other related capital assets and subsequently finance those purchases through capital leases. The capital leases are secured by the related assets. Laboratory and manufacturing equipment are financed over 48 months and all other equipment are financed over 36 months. Interest rates vary in accordance with changes in the three and four year treasury rates. As of March 31, 2007, \$4.2 million was outstanding (\$2.0 million classified as current liabilities and \$2.2 million as long-term liabilities).

The Master Security Agreement, which previously had been extended, expired October 31, 2006. GECC has agreed in the near term to discuss our capital financing needs and we are also seeking alternative capital financing arrangements. We cannot give you assurances that we will receive additional financing from GECC or secure an alternate source to finance our capital lease needs in the future.

In connection with the restructuring of the PharmaBio loan, on October 25, 2006, pursuant to an amendment to the Master Security Agreement, GECC consented to our restructuring the PharmaBio loan and, in consideration of GECC's consent and other amendments to the Master Security Agreement, we granted to GECC, as additional collateral under the Master Security Agreement, a security interest in the same assets that comprise the PharmaBio Collateral (GECC Supplemental Collateral). GECC retains a first priority security interest in the property and equipment financed under the Master Security Agreement, which are not a part of the PharmaBio Collateral. GECC has agreed to release its security interest in the GECC Supplemental Collateral upon: (a) receipt by us of FDA approval for Surfaxin for the prevention of RDS in premature infants or (b) the occurrence of certain milestones to be agreed.

Included in the outstanding balance with GECC, in December 2005, we financed \$2.4 million pursuant to our capital lease financing arrangement to support the purchase of our manufacturing operations in Totowa, NJ, which was classified as a note payable on the Consolidated Balance Sheets (of which \$0.7 million is current and \$1.0 million is long-term as of March 31, 2007). The note has an interest rate of 10.3% and is repayable over a 48-month period. The note payable is secured by equipment at the manufacturing facility in Totowa, NJ.

## 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. In April 2007, the lease, which originally expired in February 2010 with total aggregate payments of \$4.6 million, was extended an additional three years through February 2013 with additional payments of \$3.0 million over the extension period.

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.

In August 2006, we reduced our leased office and analytical laboratory space in Doylestown, Pennsylvania from approximately 11,000 square feet to approximately 5,600 square feet and extended the lease that expires in August 2007 and is thereafter subject to extensions on a monthly basis.

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

If we are successful in commercializing our SRT portfolio, we expect that our needs for additional leased space will increase.

## 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, 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 with Kingsbridge, the use of which is subject to certain conditions, we currently do not have any contractual arrangements under which we may obtain additional financing.

We have engaged Jefferies under an arrangement that expires in June 2007 to assist us in identifying and evaluating strategic alternatives intended to enhance the future growth potential of our SRT pipeline and maximize shareholder value. In November 2006, we raised \$10 million in a private placement transaction and, in April 2007, we raised \$30.2 million in a registered direct offering. We continue to evaluate a variety of strategic transactions, including, but not limited to, potential business alliances, commercial and development partnerships, financings and other similar opportunities, although we cannot assure you that we will enter into any specific actions or transactions.

If a transaction involving the issuance of additional equity and debt securities is concluded, such a transaction may result in additional dilution to our shareholders. We cannot be certain that additional funding will be available when needed or on terms acceptable to us, if at all. If we fail to receive additional funding or enter into business alliances or other similar opportunities, we may have to reduce significantly the scope of or discontinue our planned research, development and manufacturing 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, does not expect that our disclosure controls or our 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 our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our Chief Executive Officer and our 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, our Chief Executive Officer and our Chief Financial Officer concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective in their design to ensure that information required to be disclosed by us 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 March 15, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant’s motion to dismiss the Second Consolidated Amended Complaint filed by the Mizla Group, individually and on behalf of a class of investors who purchased the Company’s publicly traded securities between March 15, 2004 and June 6, 2006, alleging securities laws-related violations in connection with various public statements made by the Company. The amended complaint had been filed on November 30, 2006 against the Company, its Chief Executive Officer, Robert J. Capetola, and its former Chief Operating Officer, Christopher J. Schaber, under the caption “In re: Discovery Laboratories Securities Litigation” and sought an order that the action proceed as a class action and an award of compensatory damages in favor of the plaintiffs 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. On April 10, 2007, plaintiffs filed a Notice of Appeal with the United States District Court for the Eastern District of Pennsylvania.

On May 1, 2007, the United States District Court for the Eastern District of Pennsylvania granted defendant's motion to dismiss the consolidated shareholder derivative complaint that was filed on December 29, 2006 under the caption "In re: Discovery Laboratories Derivative Litigation." The complaint named as defendants the Company's Chief Executive Officer, Robert J. Capetola, and Herbert H. McDade, Jr., Antonio Esteve, Max E. Link, Marvin E. Rosenthale, W. Thomas Amick, all directors of the Company, and Christopher J. Schaber, the Company's former Chief Operating Officer and sought an award of damages, disgorgement of profits, injunctive and other equitable relief and award of attorneys' fees and costs. The plaintiffs were granted leave to file a second amended complaint by May 15, 2007.

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

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

**ITEM 1A. RISK FACTORS**

In addition to the risks, uncertainties and other factors set forth herein, see the "Risk Factors" section contained in our most recent Annual Report on Form 10-K.

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

During the three months ended March 31, 2007, we did not issue any unregistered shares of common stock pursuant to the exercise of outstanding warrants and options. There were no stock repurchases in the three months ended March 31, 2007.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

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

**SIGNATURES**

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

Discovery Laboratories, Inc.  
(Registrant)

Date: May 10, 2007

By: /s/ Robert J. Capetola

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

Date: May 10, 2007

By: /s/ John G. Cooper

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

## INDEX TO EXHIBITS

The following exhibits are included with this Annual Report on Form 10-K. All management contracts or compensatory plans or arrangements are marked with an asterisk.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
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	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.
3.3	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.
3.4	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.
3.5	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.
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 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.
4.3	Form of Class A Investor Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 20, 2003.
4.4	Class B Investor Warrant dated July 7, 2004, issued to Kingsbridge Capital Limited.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on July 9, 2004.
4.5	Warrant Agreement, dated as of November 3, 2004, by and between Discovery and QFinance, Inc.	Incorporated by reference to Exhibit 4.1 of Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2004.

4.6	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 21, 2006.
4.7	Registration Rights Agreement, dated as of July 7, 2004, by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2004.
4.8	Registration Rights Agreement, dated as of April 17, 2006, 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 April 21, 2006.
4.9	Second Amended and Restated Promissory Note, dated as of October 25, 2006, issued to PharmaBio Development Inc. ("PharmaBio")	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.10	Warrant Agreement, dated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.11	Warrant Agreement, dated November 22, 2006	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
10.31	Amended and Restated Employment Agreement, dated as of May 4, 2006, by and between Discovery and Thomas Miller, Ph.D.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 27, 2007.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.



## CERTIFICATIONS

I, Robert J. Capetola, certify that:

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

Date: May 10, 2007

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

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## CERTIFICATIONS

I, John G. Cooper, certify that:

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

Date: May 10, 2007

/s/ John G. Cooper  
John G. Cooper  
Executive Vice President and Chief Financial Officer

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## CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2007 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2007

/s/ Robert J. Capetola

Robert J. Capetola, Ph.D.

President and Chief Executive Officer

/s/ John G. Cooper

John G. Cooper

Executive Vice President and Chief Financial Officer

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

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

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