

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

FORM 10-Q

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

For the quarterly period ended September 30, 2008

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, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

As of November 7, 2008, 100,485,194 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, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations; plans regarding our efforts to gain U.S. regulatory approval for our lead product, Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome in premature infants, and the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our Surfactant Replacement Therapies (SRT) technology and our aerosolization systems, including our capillary aerosolization technology, including planning for and timing of any clinical trials and potential development milestones; our plans related to the establishment of our own commercial and medical affairs capabilities to support the launch of Surfaxin in the United States, if approved, and our other products; the development of financial, clinical, manufacturing and distribution plans related to the potential commercialization of our drug products; plans regarding potential strategic alliances and collaboration arrangements with pharmaceutical companies and others to develop, manufacture and market our products.

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 our recently filed Complete Response to the May 2008 Approvable Letter that we received from the U. S. Food and Drug Administration (FDA) for Surfaxin will not satisfy the FDA;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;
- risks relating to the rigorous regulatory approval processes, including pre-filing activities, required for approval of any drug or combination drug-device products that we may develop, whether independently, with development partners or pursuant to collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- risks relating to our research and development activities, which involve time-consuming and expensive pre-clinical studies, multi-phase clinical trials and other studies and other efforts, and which may be subject to potentially significant delays or regulatory holds, or fail;
- risks relating to our ability to develop and manufacture drug products and aerosolization systems, including systems based on our novel capillary aerosolization technology, for initiation and completion of our clinical studies, and, if approved, commercialization of our drug and combination drug-device products.
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers and assemblers;
- the risk that we, our contract manufacturers or any of our third-party suppliers encounter problems or delays manufacturing or assembling drug products, drug substances, aerosolization devices and related components and other materials on a timely basis or in an amount sufficient to support our development efforts and, if our products are approved, commercialization;
- the risk that, if approved, we may be unable, for reasons related to market conditions, the competitive landscape or otherwise, to successfully launch and profitably sell our products;
- risks relating to our ability to develop a successful sales and marketing organization to market Surfaxin, if approved, and our other product candidates, in a timely manner, if at all, and that we or our marketing and advertising consultants will not succeed in developing market awareness of our products or that our product candidates will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;

- the risk that we or our development partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;
- the risk that we may not be able to raise additional capital or enter into collaboration agreements (including strategic alliances for development or commercialization of our Surfactant Replacement Therapies (SRT) and combination drug-device products);
- risks that financial market conditions may change, including that the ongoing credit crisis could adversely affect our ability to fund our activities, additional financings could result in equity dilution, or that we will be unable to maintain The Nasdaq Global Market listing requirements, causing the price of our shares of common stock to decline;
- the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;
- the risks that we may be unable to maintain and protect the patents and licenses related to our SRT; other companies may develop competing therapies and/or technologies or health care reform may adversely affect us;
- the risk that we may become involved in securities, product liability and other litigation;
- risks relating to reimbursement and health care reform;
- 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. After gaining approval of a drug product, pharmaceutical companies face considerable challenges in marketing and distributing their products, and may never become profitable.

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

	September 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 26,925	\$ 36,929
Available-for-sale marketable securities	4,534	16,078
Prepaid expenses and other current assets	221	611
Total Current Assets	31,680	53,618
Property and equipment, net	6,324	7,069
Restricted cash	600	600
Deferred financing costs and other assets	1,045	1,457
Total Assets	<u>\$ 39,649</u>	<u>\$ 62,744</u>
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,429	\$ 757
Accrued expenses	5,837	7,087
Equipment loans, current portion	2,999	2,625
Total Current Liabilities	11,265	10,469
Loan payable, including accrued interest	10,024	9,633
Equipment loans, non-current portion	1,338	2,991
Other liabilities	866	870
Total Liabilities	23,493	23,963
Stockholders' Equity:		
Common stock, \$0.001 par value; 180,000 shares authorized; 99,884 and 96,953 shares issued; and 99,571 and 96,640 shares outstanding at September 30, 2008 and December 31, 2007, respectively.	100	97
Additional paid-in capital	337,971	329,999
Accumulated deficit	(318,871)	(288,303)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Other comprehensive income	10	42
Total Stockholders' Equity	<u>16,156</u>	<u>38,781</u>
Total Liabilities & Stockholders' Equity	<u>\$ 39,649</u>	<u>\$ 62,744</u>

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY**Consolidated Statements of Operations**

(Unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenue from collaborative arrangement and grants	\$ 50	\$ -	\$ 4,600	\$ -
Expenses:				
Research and development	6,724	6,184	21,395	18,400
General and administrative	3,726	3,147	13,307	9,366
Total expenses	10,450	9,331	34,702	27,766
Operating loss	(10,400)	(9,331)	(30,102)	(27,766)
Other income / (expense):				
Interest and other income	142	457	800	1,321
Interest and other expense	(381)	(473)	(1,266)	(1,596)
Other income / (expense), net	(239)	(16)	(466)	(275)
Net loss	\$ (10,639)	\$ (9,347)	\$ (30,568)	\$ (28,041)
Net loss per common share - Basic and diluted	\$ (0.11)	\$ (0.11)	\$ (0.31)	\$ (0.35)
Weighted-average number of common shares outstanding - basic and diluted	98,619	84,642	97,324	79,485

See notes to consolidated financial statements

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

	Nine Months Ended	
	September 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (30,568)	\$ (28,041)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,685	1,212
Stock-based compensation and 401(k) match	3,744	3,743
Loss on disposal of property and equipment	110	3
Changes in:		
Prepaid expenses and other assets	348	233
Accounts payable and accrued expenses	422	866
Other assets	3	(149)
Other liabilities and accrued interest on loan payable	387	924
Net cash used in operating activities	<u>(23,869)</u>	<u>(21,209)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(599)	(3,163)
Restricted cash	—	183
Purchases of marketable securities	(23,722)	(26,800)
Proceeds from sales or maturity of marketable securities	35,234	13,211
Net cash provided by/(used in) investing activities	<u>10,913</u>	<u>(16,569)</u>
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	4,231	30,224
Proceeds from equipment loans	896	5,509
Principal payments under equipment loan obligations	(2,175)	(5,297)
Net cash provided by financing activities	<u>2,952</u>	<u>30,436</u>
Net decrease in cash and cash equivalents	(10,004)	(7,342)
Cash and cash equivalents - beginning of period	36,929	26,173
Cash and cash equivalents - end of period	<u>\$ 26,925</u>	<u>\$ 18,831</u>
Supplementary disclosure of cash flows information:		
Interest paid	\$ 420	\$ 511
Non-cash transactions:		
Unrealized (loss)/gain on marketable securities	(32)	20

See notes to consolidated financial statements

Note 1 – The Company and Basis of Presentation

The Company

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

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. We have filed with the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for our initial product, Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established April 17, 2009 as its target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review of this NDA. (See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Plan of Operations.”) We are also developing Surfaxin for other neonatal and pediatric respiratory conditions and disorders, such as Acute Respiratory Failure (ARF), for which we are conducting a Phase 2 clinical trial in children up to two years of age, and Bronchopulmonary Dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. Aerosurf[™] is our proprietary SRT in aerosolized form and is being developed for the treatment of RDS in premature infants. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of SRT in respiratory medicine.

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

We have implemented a business strategy that includes focusing primarily on efforts intended to potentially gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States, and, as we work towards this milestone, conserving our financial resources. Our strategy also includes (i) selective investment in our SRT pipeline programs, including life-cycle development of Surfaxin for other respiratory conditions prevalent in the NICU and PICU, new SRT formulation development, and Aerosurf for neonatal and pediatric conditions; (ii) taking actions to establish our own commercial organization specialized in neonatal and pediatric indications to prepare for and execute the launch of Surfaxin in the United States; (iii) seeking collaboration agreements and strategic partnerships in the international and domestic markets for the development and potential commercialization of our SRT pipeline, including Surfaxin and Aerosurf; (iv) continued investment in our quality systems and manufacturing capabilities to meet the anticipated pre-clinical, clinical and potential future commercial requirements of Surfaxin, Aerosurf and our other SRT products; and (v) seeking investments of additional capital, including potentially from business alliances, commercial and development partnerships, equity financings and other similar opportunities, although there can be no assurance that we will identify or enter into any specific alliances or transactions.

Basis of Presentation

The accompanying interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. 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 our Annual Report on Form 10-K for the year ended December 31, 2007.

Note 2 – Accounting Policies and Recent Accounting Pronouncements

Accounting Policies

There have been no changes to our critical accounting policies since December 31, 2007. For more information on critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2007. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

Recent Accounting Pronouncements

In December 2007, the FASB ratified EITF Issue No. 07-1, "Accounting for Collaborative Arrangements." EITF 07-1 requires certain income statement presentation of transactions with third parties and of payments between parties to the collaborative arrangement, along with disclosure about the nature and purpose of the arrangement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the impact of the pending adoption of EITF 07-1 on our consolidated financial statements.

In June 2007, the FASB ratified EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities." EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. EITF Issue No. 07-3 was effective for our fiscal year beginning January 1, 2008 and does not have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities," which is effective for financial statements issued for fiscal years beginning after November 15, 2007. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The Statement also establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of a company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which a company has chosen to use fair value on the face of the balance sheet. SFAS 159 was effective for our fiscal year beginning January 1, 2008 and does not have a material impact on our financial statements.

In September 2006, the FASB issued SFAS No.157, "Fair Value Measurements" (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. SFAS 157 requires expanded information about the extent to which a company measures assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 was effective for our fiscal year beginning January 1, 2008 and does not have a material impact on our financial statements. See Note 7, Fair Value Measurements.

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 \$10.6 million and \$30.6 million for the three and nine months ended September 30, 2008, respectively, and \$9.3 million and \$28.0 million for the three and nine months ended September 30, 2007. Total comprehensive loss consists of the net loss and unrealized gains and losses on marketable securities.

Note 5 – Revenue from Collaborative Arrangement and Grants

Revenue from collaborative arrangement is associated with the March 2008 restructuring of our strategic alliance agreement with Philip Morris USA Inc. d/b/a Chrysalis Technologies (Chrysalis). Under the modified agreement, Chrysalis agreed to pay us \$4.5 million to support future development of our capillary aerosolization technology, of which \$2.0 million became payable upon execution in March 2008 of the modified agreement and \$2.5 million became payable upon completion of a technology transfer to us in June 2008. Additionally, as of September 30, 2008, we had received \$100,000 from the Commonwealth of Pennsylvania, Department of Community and Economic Development (the Department), as an opportunity grant under a jobs creation program.

Note 6 – Working Capital

We have incurred substantial losses since inception and expect to continue to make significant investments in continued product research, development, manufacturing and, in anticipation of potential marketing approval of our SRT products, commercialization activities. Historically, we have funded our operations primarily through the issuance of equity securities, debt and equipment financing facilities.

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

We plan to fund our research, development, manufacturing and preparatory 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 and our other SRT, if approved;
- equipment financings; and
- interest earned on invested capital.

Our capital requirements will depend on many factors, including the success of our product development and, if approved, our commercialization plans. Even if we succeed in developing and subsequently commercializing product candidates, we may never generate sufficient sales revenue to achieve or maintain profitability.

We have Committed Equity Financing Facilities (CEFFs) that we entered into on May 22, 2008 (2008 CEFF) and April 17, 2006 (2006 CEFF). Each of the 2008 CEFF and the 2006 CEFF allows us to raise capital for a period of three years ending June 19, 2011 and May 12, 2009, respectively, at the time and in amounts deemed suitable to us. Our shares of common stock are issued at a predefined discount based on the volume weighted-average price of our common stock (VWAP) on each trading day. Use of each CEFF is subject to certain conditions, including aggregate share and dollar limitations, draw down limitations and minimum daily price restrictions. As of September 30, 2008, under the 2008 CEFF and 2006 CEFF approximately 17.2 million shares and 4.5 million shares, respectively, were potentially available for issuance (provided, however, that, under the 2006 CEFF, the closing price of our common stock on the trading day immediately preceding the draw down period must be at least \$2.00). See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility” and our most recent Annual Report on Form 10-K at “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility (CEFF)”. We anticipate using our CEFFs, when available, to support our working capital needs and maintain cash availability in 2008.

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 there can be no assurance that we will be able to obtain additional capital when needed and on acceptable terms, if at all.

Note 7 – Fair Value Measurements

Effective January 1, 2008, we adopted SFAS No. 157 (*Fair Value Measurements*). SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements.

Under SFAS 157, fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 – Quoted prices in active markets for identical assets and liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The adoption of this statement did not have a material effect on our results of operations and financial condition.

Fair Value on a Recurring Basis

Assets measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations as of September 30, 2008.

Assets	Fair Value	Fair value measurement using		
	September 30, 2008	Level 1	Level 2	Level 3
Money Markets and Certificates of Deposit	\$ 21,525	\$ 21,525	\$ -	\$ -
Commercial Paper	8,085	-	8,085	-
Restricted Cash	600	600	-	-
Total	<u>\$ 30,210</u>	<u>\$ 22,125</u>	<u>\$ 8,085</u>	<u>\$ -</u>

In addition to the amounts reported in the table above, we also held \$1.9 million in operating cash as of September 30, 2008.

Note 8 – Debt

In September 2008, we received a \$500,000 loan from the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department), Machinery and Equipment Loan Fund (MELF Loan) under a jobs creation program to fund the purchase and installation of new machinery and equipment or the upgrade of existing machinery and equipment at our new analytical and development laboratory in Warrington, Pennsylvania. The MELF Loan is secured by the purchased equipment, is to be repaid over seven years and accrues interest at a rate of 5% per annum. In connection with this loan, we paid a commitment fee of \$5,000. Under the MELF Loan, we must retain seven employees and create 25 new positions at our new laboratory within three years. If we fail to comply with this requirement, the interest rate on the MELF Loan will be increased to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term.

Note 9 – Stock-Based Employee Compensation

We use the Black-Scholes option pricing model to determine the fair value of stock options and amortize 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 our 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 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:

	September 30, 2008	September 30, 2007
Expected volatility	77%	95%
Expected term	4 and 5 years	4 and 5 years
Risk-free interest rate	3.4% - 3.5%	4.6%
Expected dividends	–	–

The total employee stock-based compensation for the three and nine months ended September 30, 2008 and 2007 was as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research & Development	\$ 389	\$ 319	\$ 1,081	\$ 1,109
General & Administrative	764	737	2,310	2,343
Total	<u>\$ 1,153</u>	<u>\$ 1,056</u>	<u>\$ 3,391</u>	<u>\$ 3,452</u>

As of September 30, 2008, there was \$6.6 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Amended and Restated 1998 Stock Incentive Plan (1998 Plan) and the 2007 Long-Term Incentive Plan. That cost is expected to be recognized over a weighted-average vesting period of 1.84 years.

As of September 30, 2008, 55,913 restricted stock awards were issued and outstanding under the 1998 Plan.

Note 10 – Subsequent Events

On October 17, 2008, we submitted our Complete Response to the FDA's May 2008 Approvable Letter for Surfaxin for the prevention of RDS in premature infants. The FDA has established April 17, 2009 as its target action date to complete its review of this NDA.

In October 2008, we completed a financing pursuant to the 2008 CEFF resulting in gross proceeds of approximately \$1.3 million from the issuance of 913,827 shares of our common stock at an average price per share, after the applicable discount, of \$1.44.

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

Our SRT pipeline is focused initially on the most significant respiratory conditions prevalent in the NICU and PICU. We have filed with the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for our initial product, Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established April 17, 2009 as its target action date to complete its review of this NDA. (See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Plan of Operations.") We are also developing Surfaxin for other neonatal and pediatric respiratory conditions and disorders, such as Acute Respiratory Failure (ARF), for which we are conducting a Phase 2 clinical trial in children up to two years of age, and Bronchopulmonary Dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. Aerosurf[™] is our proprietary SRT in aerosolized form and is being developed for the treatment of RDS in premature infants. Aerosurf has the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of SRT in respiratory medicine.

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

We have implemented a business strategy that includes:

- focusing primarily on efforts intended to potentially gain regulatory approval to market and sell Surfaxin for the prevention of RDS in premature infants in the United States, and, as we work towards this milestone, conserving our financial resources;
- selective investment in our SRT pipeline programs, including life-cycle development[®] of Surfaxin for other respiratory conditions prevalent in the NICU and PICU, new SRT formulation development, and Aerosurf for neonatal and pediatric conditions;

- taking actions to establish our own commercial organization specialized in neonatal and pediatric indications to prepare for and execute the launch of Surfaxin in the United States;
- seeking collaboration agreements and strategic partnerships in the international and domestic markets for the development and potential commercialization of our SRT pipeline, including Surfaxin and Aerosurf, although there can be no assurance that we will succeed in entering into such an arrangement;
- continued investment in our quality systems and manufacturing capabilities, including our manufacturing operations in Totowa, New Jersey and our recently-completed analytical laboratories in Warrington, Pennsylvania. We plan to manufacture sufficient drug product to meet the anticipated pre-clinical, clinical, formulation development and potential future commercial requirements of Surfaxin, Aerosurf and our other SRT product candidates. To support our formulation development activities, we plan to enter into arrangements with one or more contract manufacturing organizations. For our aerosolized SRT, we plan to collaborate with engineering device experts and use contract manufacturers to produce aerosol devices and related components to meet our development and potential future commercial requirements. Our long-term manufacturing strategy includes potentially entering into arrangements with contract manufacturing organizations, expanding our existing facilities or building or acquiring additional manufacturing capabilities for the production and development of our proprietary SRT drug and combination drug-device combination products; and
- seeking investments of additional capital, including potentially from business alliances, commercial and development partnerships, equity financings and other similar opportunities, although there can be no assurance that we will identify or enter into any specific alliances or transactions.

Since our inception, we have incurred significant losses and, as of September 30, 2008, we had an accumulated deficit of \$318.9 million (including historical results of predecessor companies). The majority of our expenditures to date have been for 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 September 30, 2008, we had: (i) cash and marketable securities of \$31.5 million; (ii) approximately 17.2 million shares potentially available for issuance, up to an aggregate of approximately \$56.9 million, under a May 2008 Committed Equity Financing Facility (2008 CEFF) with Kingsbridge Capital Limited (Kingsbridge), subject to certain conditions, including that the volume weighted-average price of our common stock (VWAP) on each trading day must be at least equal to the greater of \$1.15 or 90% of the closing price of our common stock on the trading day immediately preceding the draw down period (see “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility”); (iii) approximately 4.5 million shares potentially available for issuance, up to an aggregate of approximately \$34.3 million, under an April 2006 Committed Equity Financing Facility with Kingsbridge (2006 CEFF), subject to certain conditions, including that the VWAP on each trading day must be at least equal to the greater of \$2.00 or 85% of the closing price of our common stock on the trading day immediately preceding the draw down period (see our most recent Annual Report on Form 10-K, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility”); (iv) approximately \$10.0 million outstanding (\$8.5 million principal and \$1.5 million of accrued interest as of September 30, 2008) on a loan from PharmaBio Development Inc. d/b/a NovaQuest (PharmaBio), the strategic investment group of Quintiles Transnational Corp., the principal amount of which is due and payable, together with all accrued and unpaid interest on April 30, 2010; (v) \$3.8 million outstanding under our equipment financing facility with GE Business Financial Services Inc. (GE), and (vi) \$0.5 million outstanding under an equipment loan from the Commonwealth of Pennsylvania, Department of Community and Economic Development, Machinery and Equipment Loan Fund (MELF). 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 and nine months ended September 30, 2008 were \$6.7 million and \$21.4 million, respectively. Research and development expenses for the three and nine months ended September 30, 2007 were \$6.2 million and \$18.4 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 our manufacturing operations, formulation development, development of aerosolized SRT, and research, clinical, regulatory and other direct preclinical and clinical projects.

These cost categories typically include the following expenses:

Manufacturing Development

Manufacturing development primarily reflects costs to: (i) maintain our manufacturing operations in Totowa, New Jersey and our quality assurance and analytical chemistry capabilities in Totowa and at our recently completed analytical and development laboratories at our headquarters in Warrington, Pennsylvania, to assure adequate production of clinical and potential commercial drug supply for our SRT programs, including Surfaxin, if approved, in conformance with current good manufacturing practices (cGMP) (these costs include employee expenses, depreciation, costs of drug substances, quality control and assurance activities and analytical services); (ii) design, develop, manufacture and assemble aerosolization systems to administer Aerosurf, including the initial prototype version and the next-generation version of our novel capillary aerosolization system, and (iii) develop new formulations of our SRT.

Development Operations (unallocated)

Development operations include (i) clinical, regulatory and biostatistics activities for the management of our clinical trial programs in accordance with current good clinical practices (cGCP) and (ii) medical affairs capabilities, including medical science liaisons, to provide scientific and medical education support in connection with the potential commercial launch of Surfaxin and other products in our SRT pipeline. These costs include personnel, supplies, facilities, fees to consultants, other related costs of clinical trials and management, clinical quality control and regulatory compliance activities, data management and biostatistics.

Direct Pre-Clinical and Clinical Program Expenses

Direct pre-clinical and clinical program expenses include (i) pre-clinical activities prior to initiation of any potential human clinical trials and (ii) activities associated with conducting human clinical trials, including patient enrollment costs, external site costs, costs of clinical drug supply and related external costs such as contract research consultant fees and expenses, and (iii) activities associated with obtaining data and other information included in our Complete Responses to the April 2006 and May 2008 Approvable Letters.

The following summarizes our research and development expenses by each of the foregoing categories for the three and nine months ended September 30, 2008 and 2007:

<i>(in thousands)</i> Research and Development Expenses:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Manufacturing development	\$ 3,286	\$ 3,520	\$ 12,656	\$ 9,902
Development operations (unallocated)	1,910	1,724	5,900	5,251
Direct pre-clinical and clinical program expenses	1,528	940	2,837	3,247
Total Research & Development Expenses	\$ 6,724	\$ 6,184	\$ 21,393	\$ 18,400

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, 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. 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 or 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 any of our SRT is contingent on numerous risks, uncertainties and other factors, some of which are described in detail in the “Risk Factors” section contained in our most recent Annual Report on Form 10-K.

CORPORATE PARTNERSHIP AGREEMENTS

Chrysalis Technologies, a Division of Philip Morris USA Inc.

In March 2008, we restructured our December 9, 2005 Strategic Alliance Agreement (Original Alliance Agreement) with Philip Morris USA Inc., d/b/a Chrysalis Technologies (Chrysalis), which had been created to unite two complementary respiratory technologies – our peptide-containing synthetic surfactant technology with Chrysalis’ novel capillary aerosolization technology – to deliver therapeutics to the deep lung.

Under the Original Alliance Agreement, Chrysalis was primarily responsible for development activities related to its proprietary capillary aerosolization technology (the Chrysalis Technology) and we were responsible for aerosolized drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the combination drug-device products using the Chrysalis Technology (Licensed Products). Under the restructuring, we entered into an Amended and Restated License Agreement dated March 28, 2008 (U.S. License Agreement) with Chrysalis to amend and restate the Original Alliance Agreement in the United States. As Chrysalis has assigned to Philip Morris Products S.A. (PMP SA) all rights in and to the Chrysalis Technology outside of the United States (International Rights), effective March 28, 2008, we also entered into a License Agreement with PMP SA with respect to the International Rights (International License Agreement, and together with the U.S. License Agreement, the License Agreements) on substantially the same terms and conditions as the U.S. License Agreement.

We hold an exclusive license in the United States under the U.S. License Agreement and an exclusive license to the International Rights under the PMP SA License Agreement in and to the Chrysalis Technology for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions (the foregoing uses in each territory, Exclusive Field). In addition, under the U.S. License Agreement, we hold a license to use the Chrysalis Technology with other drugs to treat specified target indications in specified target populations. Our exclusive license under each License Agreement now includes, in addition to the rights we previously had, the right to develop and have developed Licensed Products in the Exclusive Field in the respective territory.

In accordance with the terms of the U.S. License Agreement, Chrysalis agreed to provide continuing development support to us through June 30, 2008 and also agreed to provide financial support for our future development activities in the amount of \$4.5 million, of which \$2.0 million became payable upon execution of the modified agreement in March 2008 and \$2.5 million became payable upon completion of a technology transfer to us (in scope sufficient to permit us to practice the Chrysalis Technology) in June 2008.

Under the Original Alliance Agreement, we were obligated to pay Chrysalis royalties based on a multi-tiered royalty structure (that escalated upon attaining collaboration product revenues greater than \$500 million and \$1 billion). Under the License Agreements, we are now obligated to pay royalties at a rate equal to a low single-digit percent of sales of products sold in the Exclusive Field in the respective territories. In connection with the exclusive undertakings of Chrysalis and PMP SA not to exploit the Chrysalis Technology in the Exclusive Field, we are obligated to pay royalties on all product sales, including sales of any aerosol devices and related components sold by us in the Exclusive Field that are based on aerosolization technology other than the Chrysalis Technology. In addition, we have agreed in the future to pay minimum royalties, but are entitled to a future reduction of royalties in an amount equal to the excess of any minimum royalty paid over royalties actually earned under the License Agreements.

Under the License Agreements, we generally own the intellectual property that we create or reduce to practice in the performance of the License Agreements or exercise of the licenses granted thereunder, except such inventions that relate primarily, in each instance, to the Chrysalis Technology (Chrysalis Technology Improvements). We are obligated to assign to Chrysalis and PMPSA all such Chrysalis Technology Improvements and all such inventions are then made subject to our rights under each License Agreement. The License Agreements also contain provisions related to the calculation and payment of royalties, record-keeping and audit rights, and prosecution of patents, and include customary representations, warranties and indemnities. Each License Agreement, unless terminated earlier will expire as follows as to each Licensed Product in each country in the respective territory, on a country-by-country basis, upon the latest of: (a) the tenth anniversary of the date of the first commercial sale of the Licensed Product; (b) the date on which the sale of such Licensed Product ceases to be covered by a claim of an issued and unexpired patent in such country, or (c) the date a generic form of the product is introduced in such country. The License Agreements may be terminated, by Chrysalis or PMPSA, as appropriate, in the event that we fail to make the payment of the minimum royalties, as provided therein, or by us, in whole or in part, in the early years following the effective date, upon payment of a termination fee. In addition, either party to each License Agreement may terminate upon a material breach by the other party (subject to a specified cure period).

PLAN OF OPERATIONS

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

Through September 30, 2008, 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 September 30, 2008, we had not generated taxable income. At December 31, 2007, net operating losses available to offset future taxable income for Federal tax purposes were approximately \$258.7 million. In addition, we had a research and development tax credit carryforward of \$6.1 million at December 31, 2007. The Tax Reform Act of 1986 (the "Act") provides for a limitation on the annual use of net operating loss and research and development tax credit carry-forwards following certain "ownership changes" (as defined by the Act) that could limit our ability to utilize these carry-forwards. As a result of, among other things, past financings, we are considered to have experienced various such ownership changes. Accordingly, our ability to utilize the foregoing carry-forwards may be limited. Additionally, because tax laws limit the time periods during which these carry-forwards may be applied against future taxes, we may not be able to take full advantage of these carry-forwards for federal and state income tax purposes. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 through 2027. In 2008, \$0.8 million of Federal net operating losses and \$18,124 of research and development tax credit carryforwards expire.

Over the next 12 to 24 months, we plan to undertake a variety of initiatives that are discussed below.

Research and Development

We will continue to focus our research, development and regulatory activities on advancing our 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 herein and those contained in the "Risk Factors" section in our most recent Annual Report on Form 10-K. Also see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Research and Development."

Our major research and development projects include:

SRT for Neonatal and Pediatric Indications

In order to address the most prevalent respiratory disorders affecting infants in the NICU and PICU, we are conducting several therapeutic programs that target respiratory conditions that have been cited as some of the most significant unmet medical needs in the neonatal and pediatric community.

Surfaxin for the Prevention of RDS in Premature Infants

On May 1, 2008, the date under the Prescription Drug User Fee Act (PDUFA) on which the FDA was to complete its review of our NDA for Surfaxin for the prevention of RDS in premature infants, we received a third Approvable Letter for this NDA. Most notably, this Approvable Letter did not contain a requirement for additional clinical trials. On October 17, 2008, we submitted our Complete Response to this Approvable Letter. The FDA designated our Complete Response as a Class 2 resubmission and has established April 17, 2009 as its target action date under PDUFA to complete its review of our Surfaxin NDA.

Prior to receiving the May 2008 Approvable Letter, we believe that we had made significant progress towards gaining regulatory approval for Surfaxin. Specifically, (i) as of March 2008, we had submitted to the FDA 12-month stability data on our Surfaxin process validation batches, (ii) also in March 2008, the FDA completed a pre-approval inspection (PAI) of our manufacturing operations at Totowa, New Jersey, and thereafter issued an Establishment Inspection Report (EIR) indicating an approval recommendation, and (iii) on April 30, 2008, as part of our NDA review, we completed labeling discussions with the FDA and agreed to a proposed Surfaxin package insert setting forth prescribing information, although the package insert will not be considered final until the FDA approves our NDA.

The May 2008 Approvable Letter included, among other things, requests (i) to further tighten or justify one acceptance criterion for the biological activity test that we previously had implemented for Surfaxin release and stability testing (Biological Activity Test), (ii) to further tighten or justify acceptance criteria for lipid drug substance impurities, (iii) to further tighten or justify 2 of the 21 physical and chemical drug product acceptance criteria that we had proposed in our October 2007 Complete Response to the April 2006 Approvable Letter, and (iv) to submit certain specified equipment and aseptic process-related validation reports. To gain clarification of certain items identified in this Approvable Letter, on May 14, we submitted an information package to the FDA and requested a meeting, which occurred by teleconference on June 18, 2008.

Based on our assessment of the May 2008 Approvable Letter, after consulting with our regulatory experts, and the our June 2008 teleconference with the FDA, with the exception of two items, we believed that we could respond to the Approvable Letter using readily available data. With respect to the two remaining items, we agreed with the FDA to provide additional confirmatory data and related information as follows:

(i) Surfaxin Biological Activity Test

A few years ago, based on discussions with the FDA, we qualified and validated the Biological Activity Test in accordance with current Good Manufacturing Practices (cGMP) and implemented it for Surfaxin release and stability testing. In addition, as agreed at a December 2006 clarification meeting with the FDA, we generated data in a well-characterized RDS animal model at a Surfaxin dose level that was the same dose used in the Surfaxin Phase 3 clinical trials (the 2007 Study). The Biological Activity Test data and the 2007 Study results supported the comparability of Surfaxin drug product used in our Surfaxin Phase 3 clinical trials to the Surfaxin drug product to be manufactured for commercial use. In addition, these data were used to propose final acceptance criteria for the Biological Activity Test and were provided to, and reviewed by, the FDA prior to the May 2008 Approvable Letter.

At the June 18, 2008 meeting, the FDA asked us to conduct an additional test with respect to the Biological Activity Test using a different dose level than historically employed for Surfaxin release and stability testing. In addition, in a side by side experiment, we conducted a study using the same RDS animal model and dose as was used in the 2007 Study. We believe that the data generated supports determination of final acceptance criteria for the Biological Activity Test, the proposed shelf life for Surfaxin and further confirms the comparability of Surfaxin drug product used in our Surfaxin Phase 3 clinical trials to the Surfaxin drug product to be manufactured for commercial use. This information was included in our recent Complete Response.

(ii) Specifications for Lipid-Related Impurities in Surfaxin Active Pharmaceutical Ingredients

Surfaxin is comprised of four active pharmaceutical ingredients (APIs); a novel peptide, a fatty acid and two phospholipids. To gain final marketing authorization by the FDA, the FDA indicated that our proposed specifications for lipid-related impurities in the two individual phospholipids must also satisfy guidance issued by the International Conference of Harmonization (ICH). The ICH generally designates threshold limits for impurities present in an API and also provides guidance for justifying specifications that exceed the designated threshold limits.

At the June 18 meeting with the FDA, we discussed justifying impurity levels for certain lipid-related impurities that exceeded the ICH designated threshold limits based upon their being present in the human lung at levels equal to or greater than those that exist in Surfaxin. The FDA requested information about the levels of these lipid-related impurities specific to the neonatal lung. In addition to reviewing the scientific literature to satisfy the FDA's request, we also consulted with lipid-experts and our phospholipids suppliers to determine whether the lipid-related impurities in question can be reduced to the ICH threshold limit. As a consequence of these efforts, we included in the Complete Response data and other information demonstrating that the two phospholipids can be produced with lipid-related impurities at levels that satisfy ICH guidelines.

In October 2004, we filed a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for clearance to market in Europe Surfaxin for the prevention and rescue treatment of RDS in premature infants. In June 2006, following the April 2006 Surfaxin process validation stability failure, we determined that we could not resolve our manufacturing issues within the regulatory time frames mandated by the EMA procedure. Consequently, in June 2006, we voluntarily withdrew the MAA without resolving with the EMA certain outstanding clinical issues related to the Surfaxin Phase 3 clinical trials. We have also consulted with regulatory experts in Europe and, if we receive approval for Surfaxin in the United States, plan to have further discussions with the EMA and potentially develop a strategy to gain approval for Surfaxin in Europe.

Surfaxin for BPD in Premature Infants

In October 2006, we announced preliminary results of our Phase 2 clinical trial for Surfaxin for the prevention and treatment of BPD, which was designed as an estimation study to evaluate the safety and potential efficacy of Surfaxin in infants at risk for BPD. We believe that these results suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD. We plan to seek scientific advice from the FDA and other regulatory agencies with respect to potential clinical trial designs to support the further development of Surfaxin for the prevention of BPD. We also may consider a collaboration arrangement with a development partner to develop and/or commercialize our SRT technology to treat this disease. We currently do not expect to pursue any alternative until after we have successfully gained FDA approval of Surfaxin for the prevention of RDS in premature infants.

In June 2007, we initiated a clinical trial to determine if restoration of surfactant with Surfaxin will improve lung function and result in a shorter duration of mechanical ventilation and NICU/PICU stay for children up to two years of age suffering with ARF. The Phase 2 clinical trial is a multicenter, randomized, masked, placebo-controlled trial that will compare Surfaxin to standard of care masked by a sham air control. Approximately 180 children (subject to sample size adjustment per protocol) under the age of two with ARF will receive standard of care and be randomized to receive either Surfaxin at 5.8 mL/kg of body weight (expected weight range up to 15 kg) or sham air control. The trial will be conducted at approximately 35-40 sites in both the Northern and Southern Hemispheres. The objective of the study is to evaluate the safety and tolerability of Surfaxin administration and to assess whether such treatment can decrease the duration of mechanical ventilation in young children with ARF. Following conclusion of the upcoming viral season in the Southern Hemisphere in the fourth quarter 2008 and initiation of enrollment in the Northern Hemisphere, we plan to assess the status of patient enrollment in this trial and determine at that time whether adjustments to our timeline, which is heavily dependent upon the strength of the viral seasons, are required. Currently, we believe that data from this trial may be available in the first half of 2009, although this timeline may be extended as we conserve our resources to focus on seeking approval of Surfaxin for the prevention of RDS in premature infants.

Aerosurf, Aerosolized SRT

Aerosurf is our first aerosolized SRT that is administered through less-invasive means and is being developed to potentially obviate the need for intubation and conventional mechanical ventilation. Aerosurf holds the promise to significantly expand the use of surfactants in respiratory medicine. We have demonstrated, through both research and feasibility studies that we can aerosolize our SRT and have completed a small Phase 2 clinical study of Aerosurf that concluded that it is feasible to administer Aerosurf through nasal continuous positive airway pressure (nCPAP) and that the treatment was generally safe and well tolerated. We are currently developing Aerosurf using the Chrysalis Technology.

Under our restructured strategic alliance with Chrysalis, we have assumed full responsibility for development of the initial prototype version of the novel capillary aerosolization system (see "Corporate Partnerships and Agreements"). Our design engineers, together with our contract manufacturers and third-party medical device experts and consultants, are working to optimize the initial prototype version of this novel capillary aerosolization system. Once specified development milestones have been achieved, we plan to file our regulatory package in support of our Phase 2 clinical program and manufacture capillary aerosolization devices and related components. In support of our regulatory package, we are executing a series of supportive pre-clinical studies. In that regard, we have also met with and received guidance from the FDA with respect to the design of our proposed Phase 2 clinical program.

We originally expected to initiate our Phase 2 clinical program utilizing this novel capillary aerosolization technology in 2008. However, as these activities require significant investments in research, engineering, device development and device manufacturing capabilities, we have found it necessary to delay certain of our planned activities as we have focused our efforts on gaining regulatory approval for Surfaxin while conserving our cash resources. As our resources permit, we expect to make judicious investments in the development of our capillary aerosolization technology, with a view to potentially finalizing our regulatory package and initiating our Phase 2a clinical program in 2009.

We have also engaged in preliminary activities to develop the next-generation capillary aerosolization system for use in potential Phase 2 and Phase 3 clinical trials for Aerosurf and, if approved, future commercial activities. For this development phase, we have been working with a leading engineering and design firm that has a successful track record of developing innovative devices for major companies in the medical and pharmaceutical industries, both in the United States and other international markets. As we have refocused our resources since receiving the May 2008 Approvable Letter on potentially gaining FDA approval for Surfaxin, we have temporarily put this effort on hold.

We believe that Aerosurf is a highly promising program because it has the potential to significantly expand the use of SRT in respiratory medicine. However, we are currently conserving our resources to focus on seeking approval of Surfaxin for the prevention of RDS in premature infants. Having recently filed our Complete Response to the May 2008 Approvable Letter and now that we have a date for the potential marketing approval for Surfaxin, we plan to develop a new timeline for this activity.

SRT for Critical Care and Hospital Indications

We are also evaluating the potential development of our proprietary synthetic peptide-containing SRT to address respiratory disorders such as CF, ALI, COPD, asthma, and other debilitating respiratory conditions.

Manufacturing

Our SRT, including Surfaxin, must be manufactured in compliance with cGMP 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 drug product stability and conformance to specifications.

We plan to invest in and support our manufacturing capabilities to produce sufficient quantities of our proprietary peptide-containing synthetic SRT to meet anticipated clinical needs and, if approved, commercial needs in the United States, Europe and other markets:

Current Manufacturing Capabilities

We have operated our own manufacturing operations at a leased facility in Totowa, New Jersey, since December 2005. We believe that this has provided us with improved control and economics for the production of clinical and commercial supply of our lead product, Surfaxin, if approved, and our SRT pipeline products.

Following the failure in April 2006 of Surfaxin process validation batches that had been manufactured for us in 2005 by our then-contract manufacturer to meet designated stability parameters, and after an investigation into the root cause of the failures and implementation of a corrective action and preventative action (CAPA) plan, we completed manufacture of three new Surfaxin process validation batches in February 2007. As of March 2008, we submitted to the FDA 12-month stability data on these new Surfaxin process validation batches. Also in March 2008, the FDA completed a pre-approval inspection (PAI) of this facility and thereafter issued an Establishment Inspection Report (EIR) indicating an approval recommendation for our Surfaxin NDA. (See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Plan of Operations – Research and Development – SRT for Neonatal Intensive Care Unit – *Surfaxin for the Prevention of RDS in Premature Infants.*")

Our manufacturing strategy includes investing in our analytical and quality systems. In October 2007, we completed construction of a new analytical and development laboratory in our headquarters in Warrington, Pennsylvania and have consolidated at this location the analytical, quality and development activities previously located in Doylestown, Pennsylvania and Mountain View, California. The activities conducted in our new laboratory include release and stability testing of raw materials as well clinical and, if approved, commercial drug product supply. We also expect to perform development work with respect to our aerosolized SRT and novel formulations of our SRT technology. The laboratory has expanded our capabilities by providing additional capacity to conduct analytical testing as well as opportunities to leverage our newly-consolidated professional expertise across a broad range of projects, improving both operational efficiency and financial economics.

Long-Term Manufacturing Capabilities

We are planning to have manufacturing capabilities, primarily through our manufacturing operations in Totowa, New Jersey, that should allow for sufficient production of drug product to supply (i) the potential worldwide commercial demand for Surfaxin for our RDS program, if approved, (ii) the preclinical and clinical and, if approved, potential worldwide commercial demand for Surfaxin for our ARF and BPD programs, and (iii) the anticipated preclinical and clinical and, if approved, potential worldwide commercial demand for Aerosurf. We are also planning to use one or more contract manufacturers to support development of potential new formulations of our SRT technology.

Owning our own manufacturing operations in Totowa is an initial step in our manufacturing strategy to support the continued development of our SRT portfolio, including life cycle management of Surfaxin for new indications, optimization of our current SRT formulation as well as the development of new formulations and dosage forms, and expansion of our aerosol SRT products, beginning with Aerosurf. The lease for our Totowa facility expires in December 2014. In addition to customary terms and conditions, the lease is subject to a right of the landlord, first after December 2007 and upon two years' prior notice, to terminate the lease early. This termination right is subject to certain conditions, including that the master tenant, a related party of the landlord, must have ceased all activities at the premises, and, in the earlier years, if we satisfy certain financial conditions, the landlord must make payments to us of significant early termination amounts. Currently, our long-term manufacturing strategy includes (i) potentially renegotiating our current lease to amend the termination and other provisions, (ii) building or acquiring additional manufacturing capabilities for the production of our SRT drug products, and (iii) potentially using contract manufacturers, for the production of our SRT drug products.

Aerosol Devices and Related Componentry

To manufacture capillary aerosolization devices and related components for our planned Phase 2 Aerosurf clinical trials, we expect to utilize third-party contract manufacturers, suppliers and integrators. The manufacturing process involves assembly of key device sub-components that comprise the aerosolization systems, including the aerosol-generating device, disposable dose delivery packets, which must be assembled in a clean room environment, and patient interface systems to administer our aerosolized SRT. Under our manufacturing plan, third-party vendors will manufacture customized parts for us and assemble the key device sub-components and ship them to one central location for final assembly and integration into the aerosolization system. Once assembled, the critical drug product-contact components and patient interface systems will be packaged and sterilized. The assembled aerosolization systems will be quality-control tested prior to release for use in our clinical trials. We have entered into a Master Services Agreement with Kloehn, Inc. to act as integrator of the prototype aerosol generating device sub-components and disposable dose delivery packets that we plan to use in our planned Phase 2 clinical trials.

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

Sales and Marketing

To prepare for the potential U.S. launch of Surfaxin for the prevention of RDS in premature infants, we plan to establish our own specialty pulmonary commercial organization that will initially specialize in neonatal and pediatric indications and, as products are developed, may potentially expand to adult critical care and other hospital settings. This strategy is intended to allow us to manage our own sales and marketing activities, establish a strong presence in the NICU, and optimize the economics of our business.

We expect to incur significant expenses to develop a complete U.S. commercial capability. Our pre-approval preparations have included the hiring of experienced management personnel and investment in our medical affairs capabilities to provide for increased scientific and medical education activities. We plan to hire our sales representatives only after we have received approval to market Surfaxin. We also intend to pursue potential collaboration arrangements with international partners to co-develop and/or co-commercialize our neonatal and pediatric pipeline for Surfaxin and Aerosurf.

General and Administrative

We intend to continue investing in general and administrative resources primarily to support our intellectual property portfolios (including building and enforcing our patent and trademark positions), our business development initiatives, financial systems and controls, legal requirements, 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. 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 there can be no assurance that we will enter into any specific alliances 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.

There have been no changes to our critical accounting policies since December 31, 2007. For more information on critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2007. 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 and nine months ended September 30, 2008 was \$10.6 million (or \$0.11 per share) and \$30.6 million (or \$0.31 per share), respectively. The net loss for the three and nine months ended September 30, 2007 were \$9.3 million (or \$0.11 per share) and \$28.0 million (or \$0.35 per share), respectively.

Revenue from Collaborative Arrangements and Grants

The revenue from collaborative arrangements is associated with the March 2008 restructuring of our strategic alliance with Chrysalis. Chrysalis agreed to pay us \$4.5 million to support future development of our capillary aerosolization technology, of which \$2.0 million became payable upon execution in March 2008 of the modified agreement and was paid in April 2008 and \$2.5 million became payable upon completion of a technology transfer to us in June 2008 and was paid in August 2008. For further discussion, see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Corporate Partnership Arrangements." Additionally, as of September 30, 2008, we had received \$100,000 from the Commonwealth of Pennsylvania, Department of Community and Economic Development (the Department), as an opportunity grant under a jobs creation program.

Research and Development Expenses

Research and development expenses for the three and nine months ended September 30, 2008 were \$6.7 million and \$21.4 million, respectively. Research and development expenses for the three and nine months ended September 30, 2007 were \$6.2 million and \$18.4 million, respectively. For a description of expenses and research and development activities, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Research and Development.” For a description of the clinical programs included in research and development, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Plan of Operations.”

The increase in research and development expenses for the three and nine months ended September 30, 2008 compared to the same periods in 2007 primarily reflects:

- (i) Manufacturing development activities (included in research and development expenses) to support the production of clinical and potential commercial drug supply for our SRT programs, including Surfaxin, if approved, in conformance with cGMP. Expenses associated with manufacturing development activities for the three and nine months ended September 30, 2008 were \$3.3 million and \$12.7 million, respectively. Expenses associated with manufacturing development activities for the three and nine months ended September 30, 2007 were \$3.5 million and \$9.9 million, respectively. Manufacturing development expenses primarily consist of costs to: (a) maintain our manufacturing operations and quality assurance and analytical chemistry capabilities to assure adequate production of clinical and potential commercial drug supply for our SRT programs, including Surfaxin, if approved, in conformance with cGMP; (b) design, develop, manufacture and assemble aerosolization systems to administer Aerosurf, including the initial prototype version and the next-generation version of our novel capillary aerosolization system, and (c) develop new formulations of our SRT. Included in the expenses for the three and nine months ended September 30, 2007 were activities associated with obtaining data and other information included in our Complete Response to the April 2006 Approvable Letter. The increase in manufacturing development activities for the nine months ended September 30, 2008, as compared to the same period in 2007, is primarily due to: (i) investments in our quality assurance and analytical chemistry capabilities to support the production of clinical and anticipated commercial drug supply for our SRT programs in accordance with cGMP; and (ii) activities related to the development and optimization of the initial version of the capillary aerosolization system to administer Aerosurf.
- (ii) Research and development operations to manage the development and advancement of our SRT pipeline. Expenses related to these activities for the three and nine months ended September 30, 2008 were \$1.9 million and \$5.9 million, respectively. Expenses related to these activities for the three and nine months ended September 30, 2007 were \$1.7 and \$5.3 million, respectively. These costs are primarily associated with: (i) clinical, regulatory and biostatistics activities for the management of our clinical trial programs in accordance with current good clinical practices (cGCP) and (ii) medical affairs capabilities, including medical science liaisons, to provide scientific and medical education support in connection with the potential commercial launch of Surfaxin and other products in our SRT pipeline.
- (iii) Direct pre-clinical and clinical program activities related to the advancement of our SRT pipeline. Expenses related to these activities for the three and nine months ended September 30, 2008 were \$1.5 million and \$2.8 million, respectively. Expenses related to these activities for the three and nine months ended September 30, 2007 were \$1.0 million and \$3.2 million, respectively. These expenses in 2008 and 2007 primarily include: (a) activities associated with the ongoing Phase 2 clinical trial evaluating the use of Surfaxin for ARF in children up to two years of age; (b) pre-clinical and preparatory activities for anticipated Phase 2 clinical trials for Aerosurf for the prevention and treatment of RDS in premature infants; and (c) activities associated with obtaining data and other information included in our Complete Responses to the April 2006 Approvable Letter and the May 2008 Approvable Letter.

Research and development expenses for the three and nine months ended September 30, 2008, included charges of \$0.4 million and \$1.1 million, respectively, and for the three and nine months ended September 30, 2007, included charges of \$0.3 million and \$1.1 million, respectively, associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R).

General and Administrative Expenses

General and administrative expenses for the three and nine months ended September 30, 2008 were \$3.7 million and \$13.3 million, respectively. General and administrative expenses for the three and nine months ended September 30, 2007 were \$3.1 million and \$9.4 million, respectively. General and administrative costs primarily include costs associated with executive management, business development activities, financial and legal management, management information technologies, pre-launch commercialization activities and other administrative costs.

The increase in general and administrative expenses for the three and nine months ended September 30, 2008, compared to the same periods in 2007, primarily reflects pre-launch commercialization activities in 2008 in anticipation of the potential approval of Surfaxin related to building a U. S. commercial organization. Expenditures for these activities for the three and nine months ended September 30, 2008 were \$1.1 million and \$4.2 million, respectively. We did not incur significant pre-launch commercialization expenses for the three and nine months ended September 30, 2007.

General and administrative expenses for the three and nine months ended September 30, 2008, included charges of \$0.8 million and \$2.3 million, respectively, and for the three and nine months ended September 30, 2007, included charges of \$0.7 million and \$2.3 million, respectively, associated with stock-based employee compensation in accordance with the provisions of Statement No. 123(R).

Other Income and (Expense)

Other income and (expense) for the three and nine months ended September 30, 2008 were \$(0.2) million and \$(0.5) million, respectively. Other income and (expense) for the three and nine months ended September 30, 2007 were \$0.0 million and \$(0.3) million, respectively.

Interest and other income for the three and nine months ended September 30, 2008 were \$0.1 million and \$0.8 million, respectively. Interest and other income for the three and nine months ended September 30, 2007 were \$0.5 million and \$1.3 million, respectively. The decrease for the three and nine months ended September 30, 2008 as compared to the same period last year is primarily due to lower interest income resulting from a decrease in our average cash and marketable securities.

Interest, amortization and other expenses for the three and nine months ended September 30, 2008 were \$0.4 million and \$1.3 million, respectively. Interest, amortization and other expenses for the three and nine months ended September 30, 2007 were \$0.5 million and \$1.6 million, respectively. These expenses consist of: (i) interest on the outstanding balance under the PharmaBio loan; (ii) 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 of the existing \$8.5 million loan; and (iii) interest associated with our equipment loan obligations with GE Business Financial Services Inc. 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, in anticipation of potential marketing approval of our SRT products, commercialization activities. Historically, we have funded our operations primarily through the issuance of equity securities and the use of debt and our equipment financing facility.

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 our developed products, including Surfaxin for the prevention of RDS in premature infants, 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 and our other SRT, if approved;
- equipment financings; and
- interest earned on invested capital.

Our capital requirements will depend on many factors, including the success of the product development and, if approved, our commercialization plans. Even if we succeed in developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

We have Committed Equity Financing Facilities (CEFFs) that we entered into on May 22, 2008 (2008 CEFF) and April 17, 2006 (2006 CEFF). Each of the 2008 CEFF and the 2006 CEFF allows us to raise capital for a period of three years ending June 19, 2011 and May 12, 2009, respectively, at the time and in amounts deemed suitable to us. Our shares of common stock are issued at a predefined discount based on the volume weighted-average price of our common stock (VWAP) on each trading day. Use of each CEFF is subject to certain conditions, including aggregate share and dollar limitations, draw down limitations and minimum daily price restrictions. As of September 30, 2008, under the 2008 CEFF, approximately 17.2 million shares (up to an aggregate purchase price of \$56.9 million) were potentially available for issuance, provided that the VWAP on each trading day in a draw down period must be at least equal to the greater of \$1.15 or 90% of the closing price of our common stock on the trading day immediately preceding the draw down period. As of September 30, 2008, under the 2006 CEFF, approximately 4.5 million shares (up to an aggregate purchase price of \$34.3 million) were potentially available for issuance, provided that the VWAP on each trading day in a draw down period must be at least equal to the greater of \$2.00 or 85% of the closing price of our common stock on the trading day immediately preceding the draw down period. We anticipate using our CEFFs, when available, to support our working capital needs and maintain cash availability in 2008. (For a discussion of the 2008 CEFF, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility”. For a discussion of the 2006 CEFF, see our most recent Annual Report on Form 10-K at “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility”).

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 there can be no assurance that we will be able to obtain additional capital when needed and on acceptable terms, if at all.

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2008, we had cash, cash equivalents and marketable securities of \$31.5 million, as compared to \$53.0 million as of December 31, 2007. The decrease is primarily due to \$26.7 million used in operating activities, purchases of capital expenditures and principal payments on outstanding debt offset by \$4.3 million of proceeds from financings pursuant to the CEFF and \$0.9 million of proceeds from our equipment loans.

Committed Equity Financing Facility (CEFF)

2008 CEFF

On May 22, 2008, we entered into the 2008 CEFF with Kingsbridge, in which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to \$60 million or up to 19,328,000 newly-issued shares of our common stock. The 2008 CEFF, like the 2006 CEFF, 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 June 19, 2011. We are not obligated to utilize the entire \$60 million available under this CEFF.

The purchase price of shares sold to Kingsbridge under the 2008 CEFF is at a discount ranging from 6 to 12 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”. The discount on each of these eight trading days is determined as follows:

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

* As such term is set forth in the Common Stock Purchase Agreement dated May 22, 2008 (2008 CEFF 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) \$1.15 or (ii) 90 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period, no shares will be issued with respect to that trading day and the total amount of the draw down for that pricing period will be reduced for each such trading day by one-eighth of the draw down amount that 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 3.0 percent of the closing price market value of the 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 (as defined in the 2008 CEFF Agreement) relating to our business continues for 10 trading days after Kingsbridge provides notice of such material adverse effect.

The financings completed under the 2008 CEFF are as follows:

On July 11, 2008, we completed a financing pursuant to the 2008 CEFF resulting in gross proceeds of approximately \$1.6 million from the issuance of 1,104,850 shares of our common stock at an average price per share, after the applicable discount, of \$1.41.

On July 31, 2008, we completed a financing pursuant to the 2008 CEFF resulting in gross proceeds of \$1.5 million from the issuance of 991,537 shares of our common stock at an average price per share, after the applicable discount, of \$1.51.

On October 17, 2008, we completed a financing pursuant to the 2008 CEFF resulting in gross proceeds of approximately \$1.3 million from the issuance of 913,827 shares of our common stock at an average price per share, after the applicable discount, of \$1.44.

As of October 17, 2008, there were approximately 16.3 million shares available for issuance under the 2008 CEFF (up to an aggregate purchase price of \$55.6 million) for future financings.

On May 22, 2008, in connection with the 2008 CEFF, we issued a warrant to Kingsbridge to purchase up to 825,000 shares of our common stock at an exercise price of \$2.506 per share, which is fully exercisable for a five year period beginning November 22, 2008. The warrant is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds to us, if exercised, of approximately \$2.1 million.

2006 CEFF

In April 2006, we entered into the 2006 CEFF in which Kingsbridge committed to purchase the lesser of up to \$50 million or up to 11,677,047 shares of our common stock. Use of the 2006 CEFF is subject to certain conditions, including that the VWAP on each trading day of the eight trading day pricing period must be at least equal to the greater of \$2.00 or 85% of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period. (See our most recent Annual Report on Form 10-K at "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility".)

The financings completed under the 2006 CEFF in 2008 are as follows:

On September 9, 2008, we completed a financing pursuant to the 2006 CEFF resulting in gross proceeds of approximately \$1.3 million from the issuance of 676,360 shares of our common stock at an average price per share, after the applicable discount, of \$1.85.

As of September 30, 2008, there were approximately 4.5 million shares available for issuance under the 2006 CEFF (up to an aggregate purchase price of \$34.3 million).

In 2006, in connection with the 2006 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. The warrant, which expires in October 2011, is exercisable in whole or in part for cash, except in limited circumstances, with expected total proceeds, if exercised, of approximately \$2.8 million. As of September 30, 2008, the Class C Investor Warrant had not been exercised.

In 2004, in connection with a prior Committed Equity Financing Facility with Kingsbridge (2004 CEFF) that was terminated in 2006, 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 September 30, 2008, the Class B Investor Warrant had not been exercised.

Universal Shelf Registration Statement

On June 13, 2008, we filed a universal shelf registration statement on Form S-3 (2008 Shelf Registration Statement) with the SEC for the proposed offering from time to time of up to \$150 million of our securities. Under the 2008 Shelf Registration Statement, we have the flexibility to react to market opportunities as they arise and will be able to issue and sell a variety of securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at that time. We currently have no immediate plans to sell securities under the 2008 Shelf Registration Statement.

In October 2005, we filed a universal shelf registration statement on Form S-3 (2005 Shelf Registration Statement) with the SEC for the proposed offering, from time to time, of up to \$100 million of our debt or equity securities. In December 2005, we completed a registered direct offering of 3,030,304 shares of our common stock to select institutional investors resulting in gross proceeds to us of \$20.0 million. 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. In December 2007, we completed a registered direct offering of 10,000,000 shares of our common stock to select institutional investors resulting in gross proceeds of \$25.0 million.

The 2005 Shelf Registration Statement may permit us, from time to time, to offer and sell up to an additional approximately \$24.8 million of equity or debt securities. The 2008 Shelf Registration Statement may permit us, from time to time, to offer and sell up to \$150.0 million of our securities. There can be no assurance, however, that we will be able to complete any such offerings. 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 Transnational Corp., extended to us a secured, revolving credit facility of \$8.5 to \$10.0 million in 2001. Currently, the outstanding principal, \$8.5 million, matures on April 30, 2010. Interest on the loan accrues at the prime rate, compounded annually, and from and after October 1, 2006, is payable together with the outstanding principal at maturity. We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. Our obligations to PharmaBio under the loan documents are secured by an interest in substantially all of our assets, subject to limited exceptions set forth in the related Security Agreement.

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 PharmaBio 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. In connection with 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 September 30, 2008, the warrants had not been exercised.

As of September 30, 2008, the outstanding balance under the loan was \$10.0 million (\$8.5 million of principal and \$1.5 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

Equipment Financing Facility with GE Business Financial Services Inc.

In May 2007, we entered into a Credit and Security Agreement (Credit Agreement) with GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.) (GE), as Lender, pursuant to which GE agreed to provide us a \$12.5 million facility (Facility) to fund our capital programs. Prior to May 2007, our capital financing arrangements had been primarily with the Life Science and Technology Finance Division of General Electric Capital Corporation under a Master Security Agreement dated December 20, 2002, as amended (Previous Facility). Upon execution of the Credit Agreement, we simultaneously drew down approximately \$4.0 million of the Facility to prepay all of our then-outstanding indebtedness under the Previous Facility.

On May 30, 2008, we and GE amended the Credit Agreement to extend the term of the Facility for an additional period of six months for the purpose of funding our anticipated capital investments for that period, up to \$300,000. In consideration of the extension, we agreed to pay GE \$3,500 to cover legal fees and a non-refundable consent fee. All other terms and conditions under the Credit Agreement remain unchanged. (See our most recent Annual Report on Form 10-K at "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Equipment Financing Facility".)

As of September 30, 2008, approximately \$3.8 million was outstanding under the Facility (\$2.9 million classified as current liabilities and \$0.9 million as long-term liabilities) and \$154,000 remained available for use, subject to the conditions of the Facility.

Pennsylvania Machinery and Equipment Loan Fund (MELF)

Effective as of September 8, 2008, we entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department) and executed a Promissory Note, pursuant to which the Department funded a loan to us from the Machinery and Equipment Loan Fund in the amount of \$500,000 (MELF Loan) to fund the purchase and installation of new machinery and equipment or the upgrade of existing machinery and equipment at our new analytical and development laboratory in Warrington, Pennsylvania. Principal and interest on the MELF Loan is payable in equal monthly installments over a period of seven years. Interest on the principal amount will accrue at a fixed rate per annum equal to 5.0%. We may prepay the MELF Loan at any time without penalty. In connection with this loan, we paid a commitment fee of \$5,000. Under the Security Agreement, the MELF Loan is secured by the purchased equipment.

In addition to customary terms and conditions, the MELF Agreement provides that we must (i) retain seven current employees and create 25 new positions at our new laboratory within three years, and (ii) comply with certain state-contracting requirements in completing the laboratory project. In the event that we fail to comply with the new employee requirement within the three-year period, the interest rate on the Promissory Note, except in limited circumstances, will be increased to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term.

As of September 30, 2008, approximately \$0.5 million was outstanding under the Facility (\$0.1 million classified as current liabilities and \$0.4 million as long-term liabilities).

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, analytical technical services, research and development, 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 21,000 square feet of space for our manufacturing facility in Totowa, New Jersey, at an annual rent of \$150,000. This space is specifically designed for the production of sterile pharmaceuticals in compliance with cGMP requirements and is our only manufacturing facility. The lease expires in December 2014, subject to a right of the landlord, first exercisable after December 2007 and upon two years' prior notice, to terminate the lease early. This termination right is subject to certain conditions, including that the master tenant, a related party of the landlord, must have ceased all activities at the premises, and, in the earlier years, if we satisfy certain financial conditions, the landlord must make payments to us of significant early termination amounts. The total aggregate payments over the term of the lease are \$1.4 million. For a discussion of our manufacturing strategy, see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Plan of Operations – Research and Development – Manufacturing."

We leased approximately 5,600 square feet office and analytical laboratory space in Doylestown, Pennsylvania, with an annual rent of approximately \$93,800. The lease was terminated effective July 31, 2008 and all activities at this location have been consolidated into our new laboratory space in Warrington, Pennsylvania.

We leased 16,800 square feet of office and laboratory space at our facility in Mountain View, California, at an annual rent of approximately \$275,000. In December 2007, we consolidated these activities into our new laboratory space in Warrington, Pennsylvania. The term of this lease expired without renewal or extension on June 30, 2008.

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, joint development or commercialization arrangements 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 CEFFs with Kingsbridge and our equipment financing facility with GE, the use of which are subject to certain conditions, we have no contractual arrangements under which we may obtain additional financing. 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 there can be no assurance that we will enter into any specific alliances 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

Reference is made to Item 3 of our most recent report on Form 10-K and Part II, Item 1 of our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2008 and June 30, 2008 for information concerning the dismissal of securities class action proceedings involving us and certain of our officers and directors. Although we successfully defended these actions, similar actions, based upon similar allegations, or otherwise, may be filed in the future. The potential impact of such actions, if filed, which generally seek unquantified damages, attorneys' fees and expenses, is uncertain.

In addition, we have from time to time been involved in disputes and proceedings arising in the ordinary course of business. Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. 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.

ITEM 1A. RISK FACTORS

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

Receipt of the May 2008 Approvable Letter has caused us to refocus our efforts and conserve our financial resources, which may subject us to unanticipated risks and uncertainties.

As a result of the May 2008 Approvable Letter, and the delay with respect to the timing of potentially gaining approval for Surfaxin for the prevention of RDS in premature infants, we have adopted a strategy of focusing our efforts primarily on responding to the Approvable Letter and conserving our financial resources to potentially gain approval for Surfaxin in 2009. This has caused us to reassess the level of investment and the pace of our research and development programs, including programs for Aerosurf, BPD, ARF and new formulations of our SRT. We presently anticipate that we will experience some delays in the progress of these programs. While we remain reasonably confident that we can achieve our goals, we will continue to reassess the business environment, the competitive landscape, our position within the biotechnology industry and the adequacy of our financial resources. As a consequence of our reassessment, at any time we may implement additional and potentially significant changes to our development plans and our operations as we seek to strengthen our financial and operational position. Such changes, if adopted, could prove to be disruptive and detrimental to our development programs. Moreover, consideration and planning of such strategic changes diverts management's attention and other resources from day to day operations, which subjects us to further risks and uncertainties.

Within the anticipated timeline for gaining approval for Surfaxin, we will have to raise significant additional capital to continue our existing planned research and development activities. Moreover, such additional financing could result in equity dilution.

As a result of the May 2008 Approvable Letter, we presently anticipate that we may potentially obtain approval for Surfaxin in April 2009. If we are not successful in obtaining approval within our anticipated timeline, we may not have sufficient working capital to fund the activities necessary to gain approval for Surfaxin and continue our operations and will need substantial additional funding until such time, if ever, as we are able to commercialize our Surfaxin drug product, if approved, and generate revenues. If we are unable to raise substantial additional funds through future debt and equity financings and /or collaborative ventures with potential corporate partners, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail all other activities and, ultimately, potentially cease operations.

In addition, the continued credit crisis and related instability in the global financial system may have an impact on our business and our financial condition. We may face significant challenges if conditions in the financial markets do not improve, including increased cost of capital or inability to access the capital markets at a time when we would like, or need, to access such markets.

We presently do not have arrangements to obtain any additional financing, except for the CEFFs with Kingsbridge and our equipment financing facility with GE. Any future financing could be on unattractive terms or result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Furthermore, if the market price of our common stock were to decline, we could cease to meet the financial requirements to maintain the listing of our securities on The Nasdaq Global Market.

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

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

Receipt of the May 2008 Approvable Letter delayed the FDA's review of our NDA for Surfaxin for the prevention of RDS in premature infants. We filed our Complete Response on October 17, 2008 and the FDA has classified our submission as a Class 2 resubmission with a target action date under PDUFA of April 17, 2009. Ultimately, the FDA may not approve Surfaxin for the prevention of RDS in premature infants. Any failure to obtain FDA approval or further delay associated with the FDA's review process would adversely impact our ability to commercialize our lead product and would have a material adverse effect on our business.

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

In March 2008, we restructured our collaboration arrangement with Philip Morris USA Inc., d/b/a Chrysalis Technologies (Chrysalis). We now have responsibility for the development of the Chrysalis' proprietary capillary aerosolization technology (Chrysalis Technology) and have not had development support from Chrysalis since June 30, 2008. Our future development of the Chrysalis Technology is subject to certain risks and uncertainties, including, without limitation:

- We may not be able to complete the development of the initial prototype aerosolization device, if at all, on a timely basis and such inability may delay or prevent initiation of our planned Phase 2 clinical trials;
- We will require sophisticated engineering expertise to continue the development of the Chrysalis Technology. Although we are building our own internal medical device engineering expertise and have recently begun working with a leading engineering and design firm that has a successful track record of developing innovative devices for major companies in the medical and pharmaceutical industries, there is no assurance that our efforts will be successful or that we will be able to identify other potential collaborators to complete the development of the next-generation aerosolization system and enter into agreements with such collaborators on terms and conditions that are favorable to us, and, if we are unable to identify or retain design engineers and medical device experts to support our development program, this could impair our ability to commercialize or develop our aerosolized SRT; and

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

See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Plan of Operations – Research and Development – Corporate Partnership Agreements.”

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

During the three and nine months ended September 30, 2008, we did not issue any unregistered shares of common stock pursuant to the exercise of outstanding warrants and options. There were no stock repurchases during the three and nine months ended September 30, 2008.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: November 10, 2008

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

Date: November 10, 2008

By: /s/ John G. Cooper
John G. Cooper
Executive Vice President and Chief Financial
Officer (Principal Financial Officer)

INDEX TO EXHIBITS

The following exhibits are included with this Quarterly Report on Form 10-Q.

Exhibit No.	Description	Method of Filing
3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
3.2	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 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.
4.3	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.
4.4	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.
4.5	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.

Exhibit No.	Description	Method of Filing
4.6	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.
4.7	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.
4.8	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.
4.9	Warrant Agreement dated May 22, 2008 by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on May 28, 2008.
10.1	Amendment dated July 15, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Robert Segal and Discovery.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 18, 2008
10.2	Amendment dated July 15, 2008 to the Amended and Restated Employment Agreement dated as of May 4, 2006 between Chuck Katzer 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 18, 2008
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: November 10, 2008

/s/ Robert J. Capetola

Robert J. Capetola, Ph.D.

President and Chief Executive Officer

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: November 10, 2008

/s/ John G. Cooper

John G. Cooper

Executive Vice President and Chief Financial Officer

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 September 30, 2008 (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: November 10, 2008

/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 us and will be retained by us 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.
