

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

FORM 10-Q

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

For the quarterly period ended March 31, 2009

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 May 8, 2009, 105,726,667 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 we and the U.S. Food and Drug Administration (FDA) will not be able to agree on the matters raised by the FDA in its Complete Response letter dated April 17, 2009, or the FDA may require us to conduct significant additional activities to potentially gain approval of Surfaxin;
- 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 may encounter problems or delays in 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 identify strategic partners with whom we can commercialize our products, if approved, in a timely manner, if at all, and that we, our strategic partners and 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 strategic partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;
- the risk that we may not be able in a changing financial market to raise additional capital or enter into strategic alliances or collaboration agreements (including strategic alliances for development or commercialization of our Surfactant Replacement Therapies (SRT) and combination drug-device products);
- risks that the ongoing credit crisis could adversely affect our ability to fund our activities, that our share price will not remain at a level that would permit us to access capital from our Committed Equity Financing Facilities (CEFFs) and that the CEFFs may expire before we are able to access the full dollar amount potentially available under the CEFFs, and that additional financings could result in significant equity dilution;
- the risk that we will be unable to maintain The Nasdaq Global Market listing requirements, which would likely cause 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 and that other companies may develop competing therapies and/or technologies;
- the risk that we may become involved in securities, product liability and other litigation;
- risks related to reimbursement and health care reform that may adversely affect us; and
- and other risks and uncertainties described in our most recent Annual Report on Form 10-K, as amended, and other filings with the Securities and Exchange Commission, on Forms 10-Q and 8-K, and any amendments thereto.

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)

	March 31, 2009 (Unaudited)	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 19,125	\$ 22,744
Available-for-sale marketable securities	--	2,048
Prepaid expenses and other current assets	338	625
Total Current Assets	<u>19,463</u>	<u>25,417</u>
Property and equipment, net	5,639	5,965
Restricted cash	400	600
Deferred financing costs, net and other assets	769	907
Total Assets	<u>\$ 26,271</u>	<u>\$ 32,889</u>
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,881	\$ 2,111
Accrued expenses	5,153	5,313
Equipment loans, current portion	1,810	2,442
Total Current Liabilities	<u>8,844</u>	<u>9,866</u>
Loan payable, including accrued interest	10,209	10,128
Equipment loans, non-current portion	898	1,092
Other liabilities	881	870
Total Liabilities	<u>20,832</u>	<u>21,956</u>
Stockholders' Equity:		
Common stock, \$0.001 par value; 180,000 shares authorized; 103,960 and 101,588 shares issued; and 103,647 and 101,275 shares outstanding at March 31, 2009 and December 31, 2008, respectively.	104	102
Additional paid-in capital	344,798	341,293
Accumulated deficit	(336,409)	(327,409)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Other comprehensive income	--	1
Total Stockholders' Equity	<u>5,439</u>	<u>10,933</u>
Total Liabilities & Stockholders' Equity	<u>\$ 26,271</u>	<u>\$ 32,889</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 March 31,	
	2009	2008
Revenue from collaborative arrangement and grants	\$ -	\$ 2,050
Expenses:		
Research and development	5,607	7,232
General and administrative	3,096	4,505
Total expenses	<u>8,703</u>	<u>11,737</u>
Operating loss	(8,703)	(9,687)
Other income / (expense):		
Interest and other income	5	441
Interest and other expense	(302)	(468)
Other income / (expense), net	<u>(297)</u>	<u>(27)</u>
Net loss	<u>\$ (9,000)</u>	<u>\$ (9,714)</u>
Net loss per common share - Basic and diluted	\$ (0.09)	\$ (0.10)
Weighted-average number of common shares outstanding - basic and diluted	102,093	96,649

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Three Months Ended March 31,	
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (9,000)	\$ (9,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	516	573
Stock-based compensation and 401(k) match	976	1,182
Loss on disposal of property and equipment	--	1
Changes in:		
Receivable from collaborative arrangement	--	(2,000)
Prepaid expenses and other assets	287	144
Accounts payable	(230)	1,170
Accrued expenses	(160)	(2,479)
Other assets	1	--
Other liabilities and accrued interest on loan payable	92	159
Net cash used in operating activities	<u>(7,518)</u>	<u>(10,964)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(53)	(109)
Restricted cash	200	--
Purchases of marketable securities	--	(17,773)
Proceeds from sales or maturity of marketable securities	2,047	11,405
Net cash provided by/(used in) investing activities	<u>2,194</u>	<u>(6,477)</u>
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	2,531	--
Proceeds from equipment loans	--	251
Principal payments under equipment loan obligations	(826)	(689)
Net cash provided by/(used in) financing activities	<u>1,705</u>	<u>(438)</u>
Net decrease in cash and cash equivalents	(3,619)	(17,879)
Cash and cash equivalents - beginning of period	<u>22,744</u>	<u>36,929</u>
Cash and cash equivalents - end of period	<u>\$ 19,125</u>	<u>\$ 19,050</u>
Supplementary disclosure of cash flows information:		
Interest paid	\$ 84	\$ 157
Non-cash transactions:		
Unrealized (loss)/gain on marketable securities	(1)	49

See notes to consolidated financial statements

Note 1 – The Company and Basis of Presentation

The Company

Discovery Laboratories, Inc. (referred to as “we,” “us,” or the “Company”) is a biotechnology company developing Surfactant Replacement Therapies (SRT) to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel proprietary technology (KL₄ Surfactant Technology) produces a synthetic, peptide-containing surfactant (KL₄ Surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. In addition, our proprietary capillary aerosol generating technology (Capillary Aerosolization Technology) produces a dense aerosol with a defined particle size, to potentially deliver our aerosolized KL₄ Surfactant to the deep lung. As many respiratory disorders are associated with surfactant deficiency or surfactant degradation, we believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to treat a wide range of previously unaddressed respiratory problems.

We are currently focused on developing our lead products, Surfaxin[®], Surfaxin LS[™] and Aerosurf[®], to address the most significant respiratory conditions affecting pediatric populations. We have filed with the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, our first product based on our novel KL₄ Surfactant Technology. If approved, Surfaxin will represent the first synthetic, peptide-containing surfactant approved for use in pediatric medicine. Our lyophilized formulation of our KL₄ surfactant, beginning with Surfaxin LS[™], is manufactured as a dry powder formulation and reconstituted as a liquid prior to use. Our lyophilized KL₄ surfactant will also potentially support future development of our pipeline of KL₄ surfactant-based therapies. Aerosurf is our proprietary KL₄ Surfactant in aerosolized form, which we are developing using our Capillary Aerosolization Technology initially to treat premature infants at risk for RDS. Premature infants with RDS are treated with surfactants that are administered by means of invasive endotracheal intubation and mechanical ventilation, procedures that frequently result in serious respiratory conditions and complications. With Aerosurf, if approved, it will be possible to administer surfactant into the deep lung without subjecting patients to such invasive procedures. We believe that Aerosurf has the potential to enable a significant increase in the use of SRT in pediatric medicine.

In connection with our NDA for Surfaxin, on April 17, 2009, we received a Complete Response letter from the FDA that focused primarily on certain aspects of a Surfaxin biological activity test (BAT, a quality control stability and release test) that must be addressed before the Surfaxin application can be approved. We currently believe that we have already submitted to the FDA the data necessary to respond to the questions raised and have requested an end of review meeting with the FDA, which is scheduled to occur on June 2, 2009. If the outcome of our meeting with the FDA is successful such that we can address the FDA's questions with data already submitted or limited additional data, we believe that Surfaxin may still be approved in 2009 or early 2010. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Overview.”

We plan over time to develop our KL₄ Surfactant Technology into a robust pipeline of products that will potentially address a variety of debilitating respiratory conditions in a range of patient populations, from premature infants to adults, that suffer from severe and debilitating respiratory conditions for which there currently are few or no approved therapies. We have an ongoing Phase 2 trial to potentially address Acute Respiratory Failure (ARF) in children and our plans include development of Surfaxin to potentially address Bronchopulmonary Dysplasia (BPD) in premature infants. In addition, we are conducting research and development with our KL₄ Surfactant to potentially address Cystic Fibrosis (CF), Acute Lung Injury (ALI), and other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD).

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 months ended March 31, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. 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, 2008.

Note 2 – Liquidity Risks and Management’s Plans

We have incurred substantial losses since inception due to investments in research and development, manufacturing and potential commercialization activities and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, draw downs under our Committed Equity Financing Facilities (CEFFs), capital equipment and debt facilities, and strategic alliances. We expect to continue to fund our business operations through a combination of these sources, as well as sales revenue from our product candidates, beginning with Surfaxin for RDS, if approved.

Our capital requirements will depend upon many factors, including the success of our product development and commercialization plans. We are currently focused on developing our lead KL₄ Surfactant products, Surfaxin, Surfaxin LS and Aerosurf, to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that our research and development projects will be successful, that products developed (including Surfaxin) will obtain necessary regulatory approval, that any approved product will be commercially viable, that any CEFF will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of March 31, 2009, we had cash and marketable securities of \$19.1 million. We have two CEFFs under which we potentially may raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$77.3 million. A third CEFF expires on May 12, 2009. In addition, since March 31, 2009, we have raised an additional \$2 million under the CEFFs and entered into agreements for the purchase of 14 million units of our common stock and related warrants that is expected to close on May 13, 2009 and will result in gross proceeds to us of approximately \$11.3 million. (See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities, and “– Financings Pursuant to Common Stock Offerings”). Following receipt of the Complete Response letter from the FDA, to conserve our cash resources, we implemented cost containment measures and reduced our workforce from 115 to 91 employees. The workforce reduction was focused primarily in our commercial and corporate administrative groups. We have retained the core capabilities that we need to support development of our KL₄ surfactant technology, including our quality, manufacturing and research and development resources. We expect to take a one-time charge of approximately \$0.6 million in the second quarter ending June 30, 2009 related to the workforce reduction.

The accompanying interim unaudited consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, through future debt and equity financings and /or strategic and collaborative ventures with potential partners, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In addition, if our recent registered direct offering closes as anticipated on May 13, 2009, we will have remaining approximately 300,000 shares of common stock available for issuance (and not otherwise reserved). Accordingly, we may be unable to undertake non-deminimis additional financings without first seeking stockholder approval, a process that is time consuming and could impair our ability to efficiently raise capital when needed. In that case, we may be forced to further limit development of many, if not all, of our programs and may have to grant development and/or commercialization rights in our products to third parties. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders’ interests and, in such event, the market price of our common stock may decline. The balance sheets do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

Note 3 – Accounting Policies and Recent Accounting Pronouncements

Accounting policies

There have been no changes to our critical accounting policies since December 31, 2008. For more information on critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2008. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

Net loss per common share

Basic net loss per common share is computed by dividing the net loss by the weighted average number of common shares outstanding for the periods. For the quarters ended March 31, 2009 and 2008, 24.8 million and 20.4 million shares of common stock, respectively, were potentially issuable upon the exercise of certain stock options and warrants and vesting of restricted stock awards. Due to our net loss, these potentially issuable shares were not included in the calculation of diluted net loss per share as the effect would be anti-dilutive, therefore basic and dilutive net loss per share are the same.

Comprehensive loss

Comprehensive loss consists of net loss plus the changes in unrealized gains and losses on available-for-sale securities. Comprehensive loss for the three months ended March 31, 2009 and 2008 are as follows:

(in thousands)	Three Months Ended March 31,	
	2009	2008
Net loss	\$ (9,000)	\$ (9,714)
Change in unrealized (losses)/gains on marketable securities	(1)	49
Comprehensive loss	<u>\$ (9,001)</u>	<u>\$ (9,665)</u>

Recent accounting pronouncements

In December 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-1, "Accounting for Collaborative Arrangements" (EITF Issue No. 07-1). EITF 07-1 requires certain income statement presentation of transactions with third parties and of payments between parties to the 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 adopted EITF Issue No. 07-1 on January 1, 2009; it did not have a material impact on our consolidated financial statements.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141 (revised 2007), "Business Combinations" (SFAS 141R), which is effective for financial statements issued for fiscal years beginning on or after December 15, 2008. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree, and the goodwill acquired in the business combination. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R will be applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009. The adoption of SFAS 141R had no immediate impact, however it may have an impact on the accounting for any potential future business combinations.

Note 4 – Revenue from Collaborative Arrangement and Grants

We did not earn any revenue during the three months ended March 31, 2009.

In March 2008, we restructured our strategic alliance agreement with Philip Morris USA Inc. d/b/a Chrysalis Technologies (Chrysalis). See our Annual Report on Form 10-K for the year ended December 31, 2008 – Note 12 to our Consolidated Financial Statements. 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.

Note 5 – Stockholders Equity

Committed Equity Financing Facilities

As of March 31, 2009, we had two CEFFs that we entered into on December 12, 2008 (December 2008 CEFF) and May 22, 2008 (May 2008 CEFF) that allow us to raise capital for a period of three years ending February 6, 2011 and June 18, 2011, respectively, at the time and in amounts deemed suitable to us. A third CEFF expires on May 12, 2009. Under the December 2008 CEFF, as of March 31, 2009, we had 15 million shares potentially available for issuance (up to a maximum of \$25 million), provided that the volume weighted-average price of our common stock on each trading day (VWAP) must be at least equal to the greater of (i) \$.60 or (ii) 90% of the closing price of our common stock on the trading day immediately preceding the draw down period (Minimum VWAP). Under the May 2008 CEFF, as of March 31, 2009, we had approximately 13.3 million shares potentially available for issuance (up to a maximum of \$52.3 million), provided that the VWAP on each trading day must be at least the greater of \$1.15 or the Minimum VWAP. Use of each CEFF is subject to certain other covenants and conditions, including aggregate share and dollar limitations for each draw down. See our Annual Report on Form 10-K for the year ended December 31, 2008 – “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 2009.

Financings pursuant to the CEFF

On January 16, 2009, we completed a financing pursuant to the May 2008 CEFF resulting in gross proceeds of approximately \$0.4 million from the issuance of 419,065 shares of our common stock at an average price per share, after the applicable discount, of \$1.04.

On February 18, 2009, we completed a financing pursuant to the May 2008 CEFF resulting in gross proceeds of approximately \$1.0 million from the issuance of 857,356 shares of our common stock at an average price per share, after the applicable discount, of \$1.17.

On March 31, 2009, we completed a financing pursuant to the May 2008 CEFF resulting in gross proceeds of approximately \$1.1 million from the issuance of 1,015,127 shares of our common stock at an average price per share, after the applicable discount, of \$1.08.

On April 8, 2009, we completed a financing pursuant to the December 2008 CEFF resulting in gross proceeds of approximately \$1.0 million from the issuance of 806,457 shares of our common stock at an average price per share, after the applicable discount, of \$1.24.

On May 7, 2009, we completed a financing pursuant to the December 2008 CEFF resulting in gross proceeds of approximately \$1.0 million from the issuance of 1,272,917 shares of our common stock at an average price per share, after the applicable discount, of \$0.79.

Note 6 – 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.

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 March 31, 2009.

<u>Assets</u>	Fair Value	Fair value measurement using		
	March 31, 2009	Level 1	Level 2	Level 3
Money Markets and Certificates of Deposit	\$ 16,591	\$ 16,591	\$ -	\$ -
Restricted Cash	600	600	-	-
Total	\$ 17,191	\$ 17,191	\$ -	\$ -

Note 7 – Stock Options and 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:

	March 31, 2009	March 31, 2008
Expected volatility	92%	77%
Expected term	4 and 5 years	4 and 5 years
Risk-free interest rate	1.17% - 1.35%	3.4% - 3.5%
Expected dividends	-	-

The total employee stock-based compensation for the three months ended March 31, 2009 and 2008 was as follows:

(in thousands)	Three Months Ended March 31,	
	2009	2008
Research & Development	\$ 203	\$ 332
General & Administrative	647	723
Total	\$ 850	\$ 1,055

As of March 31, 2009, there was \$5.6 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 1.83 years.

Note 8 – Subsequent Events

Regulatory Update – Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome in Premature Infants

On April 17, 2009, we received a Complete Response letter from the FDA for Surfaxin® for the prevention of RDS in premature infants. In its letter, the FDA focused primarily on certain aspects of a Surfaxin biological activity test (BAT), a quality control stability and release test. We currently believe that we have already submitted to the FDA the data necessary to respond to the questions raised and have requested an end of review meeting with the FDA, which is scheduled to occur on June 2, 2009. If the outcome of our meeting with the FDA is successful such that we can address the FDA's questions with data already submitted or limited additional data, we believe that Surfaxin may still be approved in 2009 or early 2010. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview."

Implementation of Cost Containment Measures and Reduction in Workforce

Following receipt of the Complete Response letter from the FDA, to conserve our cash resources, we implemented cost containment measures and reduced our workforce from 115 to 91 employees. We expect to take a one-time charge of approximately \$0.6 million in the second quarter ending June 30, 2009 related to the workforce reduction. See Note 2 – Liquidity and Management's Plans.

Financings Pursuant to the CEFF

On April 8, 2009 and on May 7, 2009, we completed financings pursuant to the December 2008 CEFF resulting in gross proceeds of approximately \$1.0 million for each draw from the issuance of 806,457 shares and 1,272,917 shares, respectively, of our common stock. See Note 5 – Stockholders Equity.

Financings Pursuant to the 2008 Universal Shelf

On May 8, 2009, we entered into definitive agreements with select institutional investors for the purchase of 14 million units of our common stock and warrants to purchase common stock pursuant to a registered direct public offering. The purchase price for each unit of common stock and related warrant is \$0.81 and will result in gross proceeds of approximately \$11.3 million. For each share of common stock purchased, investors will receive warrants to purchase 0.5 shares of common stock at an exercise price of \$1.15 per share. The closing of the offering is expected to take place on May 13, 2009, subject to customary closing conditions. In connection with this offering, we have agreed not to draw down on our CEFFs for a period of 30 days after the offering, and, for the 60 days following that date, agreed to an aggregate draw down limit of 2% of our outstanding common stock and have also agreed not to sell, for a period of 90 days following the entry into the definitive agreements, any of our common stock other than in connection with this offering, pursuant to employee benefit plans, or in connection with strategic alliances involving us and a strategic partner. In addition, each of our directors and select executive officers have agreed to certain lock-up provisions with regard to future sales of our common stock for a period of 90 days after the offering. The common stock issued and issuable by exercise of the warrants in connection with this offering are covered by the 2008 Universal Shelf.

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

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a biotechnology company developing Surfactant Replacement Therapies (SRT) to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel proprietary technology (KL₄ Surfactant Technology) produces a synthetic, peptide-containing surfactant (KL₄ Surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for survival and normal respiratory function. In addition, our proprietary capillary aerosol generating technology (Capillary Aerosolization Technology) produces a dense aerosol with a defined particle size, to potentially deliver our aerosolized KL₄ Surfactant to the deep lung. As many respiratory disorders are associated with surfactant deficiency or surfactant degradation, we believe that our proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products targeted to treat a wide range of previously unaddressed respiratory problems.

We are currently focused on developing our lead products, Surfaxin[®], Surfaxin LS[™] and Aerosurf[®], to address the most significant respiratory conditions affecting pediatric populations. We have filed with the U.S. Food and Drug Administration (FDA) a New Drug Application (NDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, our first product based on our novel KL₄ Surfactant Technology. If approved, Surfaxin will represent the first synthetic, peptide-containing surfactant approved for use in pediatric medicine. Our lyophilized formulation of our KL₄ surfactant, beginning with Surfaxin LS[™], is manufactured as a dry powder formulation and reconstituted as a liquid prior to use. Our lyophilized KL₄ surfactant will potentially support future development of our pipeline of KL₄ surfactant-based therapies. Aerosurf is our proprietary KL₄ Surfactant in aerosolized form, which we are developing using our Capillary Aerosolization Technology initially to treat premature infants at risk for RDS. Premature infants with RDS are treated with surfactants that are administered by means of invasive endotracheal intubation and mechanical ventilation, procedures that frequently result in serious respiratory conditions and complications. With Aerosurf, if approved, it will be possible to administer surfactant into the deep lung without subjecting patients to such invasive procedures. We believe that Aerosurf has the potential to enable a significant increase in the use of SRT in pediatric medicine.

In connection with our NDA for Surfaxin, on April 17, 2009, we received a Complete Response letter from the FDA that focused primarily on certain aspects of a Surfaxin biological activity test (BAT, a quality control stability and release test) that must be addressed before the Surfaxin application can be approved. The BAT is one of numerous methods that we employ in an extensive quality surveillance program to assess product quality and stability of Surfaxin. These highly sophisticated tests monitor the quality of Surfaxin at release and through its shelf-life and represent very sensitive methods for detecting changes in product quality and identifying defective product.

In its letter, the FDA focused on whether the BAT can adequately distinguish change in Surfaxin drug product over time and whether we have adequately validated the BAT and determined its final acceptance criteria. We believe that validation of the BAT to the FDA's satisfaction would confirm the comparability of Surfaxin drug product used in the clinical trials to the commercial Surfaxin drug product. We believe that data already submitted to the FDA support the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product and demonstrate that the BAT can adequately distinguish change in Surfaxin over time and is an appropriate test for monitoring Surfaxin biological activity throughout its shelf-life. We have requested an end of review meeting with the FDA, which is scheduled to occur on June 2, 2009. If the outcome of our meeting with the FDA is successful such that we can address the FDA's questions with data already submitted or limited additional data, we believe that Surfaxin may still be approved in 2009 or early 2010.

Among other items in the Complete Response letter, the FDA indicated that we need to tighten one drug product specification, which we believe can readily be implemented. The Complete Response letter also contained requests to update safety and other information in the NDA as well as information requests about certain regulatory matters. In addition, the FDA approved the trade name Surfaxin.

We plan over time to develop our KL₄ Surfactant Technology into a robust pipeline of products that will potentially address a variety of debilitating respiratory conditions in a range of patient populations, from premature infants to adults, that suffer from severe and debilitating respiratory conditions for which there currently are few or no approved therapies. We have an ongoing Phase 2 trial to potentially address Acute Respiratory Failure (ARF) in children and our plans include development of Surfaxin to potentially address Bronchopulmonary Dysplasia (BPD) in premature infants. In addition, we are conducting research and development with our KL₄ Surfactant to potentially address Cystic Fibrosis (CF), Acute Lung Injury (ALI), and other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD).

Business Strategy Update

We continue to focus our efforts on potentially gaining 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, rigorously managing our financial resources while making targeted investments in research and development activities. We also continue to focus our research and development efforts on the management of RDS in premature infants, focused initially on Surfaxin, Surfaxin LS™ and Aerosurf®. We believe that Surfaxin, Surfaxin LS and Aerosurf, if approved, have the potential to advance the treatment of RDS and make it possible for many more infants at risk for RDS to be treated with SRT. Our KL₄ Surfactant Technology also has the potential to address a range of other serious and debilitating neonatal and pediatric indications, many of which represent significant unmet medical needs, potentially redefining pediatric respiratory medicine.

The following are updates to our Business Strategy (See our Annual Report on Form 10-K for the year ended December 31, 2008 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Business – Business Strategy”):

- Following receipt of the Complete Response letter from the FDA, to conserve our cash resources, we implemented cost containment measures and reduced our workforce from 115 to 91 employees. The workforce reduction was focused primarily in our commercial and corporate administrative groups. We expect to take a one-time charge of approximately \$0.6 million in the second quarter ending June 30, 2009 related to the workforce reduction. We have retained the core capabilities that we need to support development of our KL₄ surfactant technology, including our quality, manufacturing and research and development resources and continue to make investments in our proprietary KL₄ Surfactant Technology pipeline programs; and
- Although we had planned to build a fully-integrated pediatric franchise and establish our own specialty pulmonary commercial organization to initially execute the launch of Surfaxin in the United States, we have re-evaluated this strategy in light of our need to conserve our resources in response to the Complete Response letter. We now believe that it is in our best interest financially to commercialize in the United States, as well as internationally, with a strategic partner or collaboration arrangement.

We will need significant additional capital to execute our business strategy. We plan to seek infusions of capital from a variety of potential sources, including strategic alliances, equity financings, debt financings and other similar opportunities, although there can be no assurance that we will identify or enter into any specific alliances or transactions.

As of March 31, 2009, we had cash and marketable securities of \$19.1 million. We have two CEFFs under which we potentially may raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$77.3 million. A third CEFF expires on May 12, 2009. In addition, since March 31, 2009, we have raised an additional \$2 million under the CEFFS and entered into agreements for the purchase of 14 million units of our common stock and warrants to purchase common stock that are expected to close on May 13, 2009 and will result in gross proceeds to us of approximately \$11.3 million. (See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities, and "– Financings Pursuant to Common Stock Offerings"). Our capital requirements will depend upon many factors, including the success of our product development and commercialization plans. We are currently focused on developing our lead KL₄ Surfactant products, Surfaxin, Surfaxin LS and Aerosurf, to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that our research and development projects will be successful, that products developed (including Surfaxin) will obtain necessary regulatory approval, that any approved product will be commercially viable, that any CEFF will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

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, 2008. For more information on critical accounting policies, see our Annual Report on Form 10-K for the year ended December 31, 2008. Readers are encouraged to review these disclosures in conjunction with the review of this Form 10-Q.

RESULTS OF OPERATIONS

The net loss for the three months ended March 31, 2009 was \$9.0 million (or \$0.09 per share). The net loss for the three months ended March 31, 2008 was \$9.7 million (or \$0.10 per share).

Revenue from Collaborative Arrangements and Grants

We did not earn any revenue during the three months ended March 31, 2009.

In March 2008, we restructured our strategic alliance agreement with Philip Morris USA Inc. d/b/a Chrysalis Technologies (Chrysalis). (See our Annual Report on Form 10-K for the year ended December 31, 2008 – Note 12 to our Consolidated Financial Statements.) 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.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2009 and 2008 were \$5.6 million and \$7.2 million, respectively. These costs are charged to operations as incurred and are tracked by category, as follows:

(Dollars in thousands)

Three Months Ended
March 31,

Research and Development Expenses:

	<u>2009</u>	<u>2008</u>
Manufacturing development	\$ 3,487	\$ 4,366
Development operations	1,391	2,116
Direct pre-clinical and clinical programs	729	750
Total Research and Development Expenses ⁽¹⁾	<u>\$ 5,607</u>	<u>\$ 7,232</u>

(1) Included in research and development expenses for the three months ended March 31, 2009 and 2008 are charges of \$0.2 million, and \$0.4 million, respectively, associated with stock-based employee compensation in accordance with the provisions of FASB Statement of Financial Accounting Standards No. 123(R) (SFAS No. 123R).

The decrease in research and development expenses for the three months ended March 31, 2009 compared to the same period in 2008 primarily reflects:

Manufacturing Development

Manufacturing development includes: (i) manufacturing operations, quality assurance and analytical chemistry capabilities to assure adequate production of clinical and potential commercial drug supply for our KL₄ Surfactant products, in conformance with current good manufacturing practices (cGMP) (these costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities and analytical services, etc.); (ii) design and development for the manufacture of our novel capillary aerosolization systems, including an aerosol generating device, the disposable dose delivery packets and patient interface system necessary to administer Aerosurf for our anticipated Phase 2 clinical trials; and (iii) pharmaceutical development activities, including development of a lyophilized formulation of our KL₄ Surfactant.

The decrease of approximately \$0.9 million in manufacturing development expenses for the three months ended March 31, 2009, as compared to the same period in 2008, is primarily due to: (i) expenditures in the first quarter of 2008 to support our quality assurance and analytical chemistry capabilities, including implementation and validation of analytical methods and quality testing of drug product for our development programs; and (ii) a reduction in expenditures related to our efforts in the first quarter of 2009 to conserve financial resources while we focused on potentially gaining regulatory approval for Surfaxin in the United States.

Manufacturing development expenses included charges of \$0.1 million and \$0.2 million associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R for the three months ended March 31, 2009 and 2008, respectively.

Development Operations

Development operations includes scientific, clinical, regulatory, and data management/biostatistics capabilities for the execution of our product development programs, as well as medical affairs activities to provide scientific and medical education support to the pediatric community regarding our KL₄ Surfactant Technology pipeline programs. These costs include personnel, specialized consultants, outside services to support regulatory and data management activities, symposiums at key neonatal medical meetings, facilities-related costs, and other costs for the management of clinical trials.

The decrease of approximately \$0.7 million in development operations expenses for the three months ended March 31, 2009, as compared to the same period in 2008, is primarily due to (i) expenditures in the first quarter of 2008 associated with our medical affairs capabilities, including medical science liaisons and symposiums at key pediatric medical meetings in anticipation of the potential approval and commercial launch of Surfaxin in May 2008; and (ii) a reduction in expenditures related to our efforts in the first quarter of 2009 to conserve financial resources while we focused on potentially gaining regulatory approval for Surfaxin in the United States.

Development operations expenses included charges of \$0.1 million and \$0.2 million associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R for the three months ended March 31, 2009 and 2008, respectively.

Direct Pre-Clinical and Clinical Programs

Direct pre-clinical and clinical programs include: (i) pre-clinical activities, including toxicology studies and other pre-clinical studies to obtain data to support potential Investigational New Drug (IND) and NDA filings for our product candidates; and (ii) activities associated with conducting human clinical trials, including patient enrollment costs, external site costs, clinical drug supply and related external costs such as contract research consultant fees and expenses.

Direct pre-clinical and clinical programs expenses for the three months ended March 31, 2009 primarily included: (i) activities associated with the ongoing the Phase 2 clinical trials of Surfaxin for children with Acute Respiratory Failure (ARF) and aerosolized surfactant for Cystic Fibrosis; (ii) pre-clinical activities and product characterization testing of our lyophilized form of Surfaxin; and (iii) pre-clinical and preparatory activities for anticipated Phase 2 clinical trials for Aerosurf for RDS in premature infants.

Direct pre-clinical and clinical programs expenses for the three months ended March 31, 2008 primarily included: (i) activities associated with the Phase 2 clinical trial of Surfaxin for children with ARF; and (iii) pre-clinical activities for our Aerosurf program.

We plan to continue conserving our financial resources by limiting our investment in research and development programs while we focus on potentially gaining regulatory approval for Surfaxin in the United States. If we are successful in gaining approval of Surfaxin in 2009, if resources permit, we plan to accelerate investment in our KL₄ Surfactant pipeline programs and expect our research and development expenses to increase later in the year, primarily associated with development and clinical activities for our lyophilized KL₄ Surfactant and our Aerosurf program.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs of executive management, business and commercial development, finance and accounting, intellectual property and legal, human resources, information technology, facility and other administrative costs.

General and administrative expenses for the three months ended March 31, 2009 and 2008 were \$3.1 million, and \$4.5 million, respectively. General and administrative expenses included charges of \$0.6 million and \$0.7 million associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R for the three months ended March 31, 2009 and 2008, respectively.

The decrease of approximately \$1.4 million in general and administrative expenses for the three months ended March 31, 2009, as compared to the same period in 2008, is primarily due to pre-launch commercial activities in the first quarter of 2008, in anticipation of the potential approval and commercial launch of Surfaxin in May 2008. Following receipt of the May 2008 Approvable Letter, we scaled back our pre-launch commercial activities and, although we made limited investments in our commercial capabilities, we determined that we would not hire sales representatives and other marketing personnel until after we have received approval to market Surfaxin. Accordingly, throughout the remainder of 2008 and the first quarter of 2009, we continued to limit our investment in pre-launch commercial activities while we focused on potentially gaining regulatory approval for Surfaxin in the United States.

Following receipt of the Complete Response letter in April 2009, we have re-evaluated our plans to establish our own specialty pulmonary organization to commercialize our potential pediatric products, including Surfaxin, in the United States. We now believe it is in our best interest financially to commercialize in the United States, as well as internationally, with a strategic partner or collaboration arrangement, although there can be no assurance that we will be successful in entering into such an arrangement.

In addition, following receipt of the Complete Response letter from the FDA, to conserve our cash resources, we implemented cost containment measures and reduced our workforce from 115 to 91 employees. The workforce reduction was focused primarily in our commercial and corporate administrative groups. We expect to take a one-time charge of approximately \$0.6 million in the second quarter ending June 30, 2009 related to the workforce reduction.

Following the potential approval of Surfaxin, we anticipate making additional investments in the future to enhance our administrative resources, including legal, finance, business development, information technologies, human resources and general management capabilities, as and when required to meet the needs of our research and development programs and commercial activities. We also continue to plan investments to sustain and perfect our potential competitive position by maintaining our existing patent portfolio, trademarks, trade secrets and regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities, and by investing in new patents, patent extensions, new trademarks, and regulatory exclusivity designations, when available.

Other Income and (Expense)

Other income / (expenses), net was (\$0.3) million, and \$(27,000) for the three months ended March 31, 2009 and 2008, respectively, as summarized in the chart below:

	Three months ended March 31,	
	2009	2008
Interest income	\$ 5	\$ 436
Interest expense	(302)	(468)
Other income / (expense)	--	5
Other income / (expense), net	<u>\$ (297)</u>	<u>\$ (27)</u>

Interest income consists of interest earned on our cash and marketable securities. During the second half of 2008, we transitioned most of our cash and marketable securities into a treasury-based money market fund to ensure preservation of capital. The decrease in interest income in 2009 is primarily due to a significant decline in the interest rate for this fund, consistent with overall market trends. Our earned interest rates have declined from approximately 3.0% in the first quarter of 2008 to approximately 0.15% in the first quarter of 2009. Additionally, our average cash and marketable securities balance declined from \$47.3 million in the first quarter of 2008 to \$22.0 million in the first quarter of 2009.

Interest expense consists of interest accrued on the outstanding balance of our loan with PharmaBio Development Inc. ("PharmaBio"), the strategic investment group of Quintiles Transnational Corp., and under our equipment financing facilities. In addition, interest expense includes expenses associated with the amortization of deferred financing costs for warrants issued to PharmaBio in October 2006 as consideration for a restructuring of our loan in 2006. The decrease in interest expense for the three months ended March 31, 2009 as compared to the same period for 2008 is due to a decline in the variable interest rate on our PharmaBio loan and a reduction in the outstanding principal balances on our equipment loans.

LIQUIDITY AND CAPITAL RESOURCES

We have incurred substantial losses since inception, due to investments in research and development, manufacturing and potential commercialization activities and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, draw downs under our CEFFs, capital equipment and debt facilities, and strategic alliances. We expect to continue to fund our business operations through strategic alliances, a combination of the financing sources mentioned above, as well as revenue from our product candidates, beginning with Surfaxin for RDS, if approved.

Our capital requirements will depend upon many factors, including the success of our product development and commercialization plans. We are currently focused on developing our lead KL₄ Surfactant products, Surfaxin, Surfaxin LS and Aerosurf, to address the most significant respiratory conditions affecting pediatric populations. However, there can be no assurance that our research and development projects will be successful, that products developed (including Surfaxin) will obtain necessary regulatory approval, that any approved product will be commercially viable, that any CEFF will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in raising additional capital, securing strategic alliances and developing and commercializing product candidates, we may never achieve sufficient revenue to achieve or maintain profitability.

As of March 31, 2009, we had cash and marketable securities of \$19.1 million. We have two CEFFs under which we potentially may raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$77.3 million. A third CEFF expires on May 12, 2009. In addition, since March 31, 2009, we have raised an additional \$2 million under the CEFFs and entered into agreements for the purchase of 14 million units of our common stock and warrants to purchase common stock that are expected to close on May 13, 2009 and will result in gross proceeds to us of approximately \$11.3 million. (See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities, and "– Financings Pursuant to Common Stock Offerings"). Following receipt of the Complete Response letter from the FDA, to conserve our cash resources, we implemented cost containment measures and reduced our workforce from 115 to 91 employees. The workforce reduction was focused primarily in our commercial and corporate administrative groups. We have retained the core capabilities that we need to support development of our KL₄ surfactant technology, including our quality, manufacturing and research and development resources. We expect to take a one-time charge of approximately \$0.6 million in the second quarter ending June 30, 2009 related to the workforce reduction.

The accompanying interim unaudited consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, through future debt and equity financings and /or strategic and collaborative ventures with potential partners, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In addition, if our recent registered direct offering settles as anticipated on May 13, 2009, we will have remaining approximately 300,000 shares of capital stock available for issuance (and not otherwise reserved). Accordingly, we may be unable to undertake additional financings without first seeking stockholder approval, a process that is time consuming and could impair our ability to efficiently raise capital when needed. In that case, we may be forced to further limit development of many, if not all, of our programs and may have to grant development and/or commercialization rights in our products to third parties. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. The balance sheets do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

To meet our capital requirements, 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 there can be no assurance that we will take any further specific actions or enter into any transactions.

Cash Flows

We had cash, cash equivalents and marketable securities of \$19.1 million as of March 31, 2009 as compared to \$24.8 million as of December 31, 2008, a decrease of \$5.7 million. The decrease is primarily due to \$7.5 million used for operating activities and \$0.8 million used for debt service, offset by aggregate proceeds of \$2.5 million received from the issuance of 2.3 million shares of common stock pursuant to financings under our CEFFs.

Cash Flows Used in Operating Activities

Cash flows used in operating activities were \$7.5 million and \$11.0 million for the three months ended March 31, 2009 and 2008, respectively.

Our cash flows used in operating activities are a result of our net operating losses adjusted for non-cash items associated with stock-based compensation, depreciation and changes in our accounts payable, accrued liabilities and receivables.

Cash Flows from/(used in) Investing Activities

Cash flows from/(used in) investing activities included purchases of equipment of \$0.1 million and \$0.1 million for the three months ended March 31, 2009 and 2008, respectively.

Cash flows from investing activities also include cash used to purchase short-term marketable securities and cash received from the sale and/or maturity of short-term marketable securities. When assessing our cash position and managing our liquidity and capital resources, we do not consider cash flows between cash and marketable securities to be meaningful. Cash used to purchase marketable securities is subject to an investment policy that is approved by the Board of Directors and provides for the purchase of high-quality marketable securities, while ensuring preservation of capital and fulfillment of liquidity needs.

Cash Flows from/(used in) Financing Activities

Cash flows from/(used in) financing activities were \$1.7 million and \$(0.4) million for the three months ended March 31, 2009 and 2008, respectively.

Cash flows from financing activities for the three months ended March 31, 2009 included aggregate proceeds of \$2.5 million from financings pursuant to our CEFFs, offset by principal payments on our equipment loan facilities of \$0.8 million. Cash flows used in financing activities for the three months ended March 31, 2008 included \$0.3 million of proceeds from our equipment financing facilities, offset by \$0.7 million of debt service payments under our equipment loan.

Committed Equity Financing Facilities (CEFFs)

As of March 31, 2009, we had two CEFFs that we entered into on December 12, 2008 (December 2008 CEFF) and May 22, 2008 (May 2008 CEFF) that allow us to raise capital for a period of three years ending February 6, 2011 and June 18, 2011, respectively, at the time and in amounts deemed suitable to us. A third CEFF expires on May 12, 2009. Under the December 2008 CEFF, as of March 31, 2009, we had 15 million shares potentially available for issuance (up to a maximum of \$25 million), provided that the volume weighted-average price of our common stock on each trading day (VWAP) must be at least equal to the greater of (i) \$.60 or (ii) 90% of the closing price of our common stock on the trading day immediately preceding the draw down period (Minimum VWAP). Under the May 2008 CEFF, as of March 31, 2009, we had approximately 13.3 million shares potentially available for issuance (up to a maximum of \$52.3 million), provided that the VWAP on each trading day must be at least the greater of \$1.15 or the Minimum VWAP. Use of each CEFF is subject to certain other covenants and conditions, including aggregate share and dollar limitations for each draw down. See our Annual Report on Form 10-K for the year ended December 31, 2008 – “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 2009.

CEFF Financings

On January 2, 2009, we completed a financing that was initiated in 2008 under the May 2008 CEFF, resulting in proceeds of \$0.5 million from the issuance of 478,783 shares of our common stock at an average price per share, after the applicable discount, of \$1.04.

On January 16, 2009, we completed a financing under the May 2008 CEFF, resulting in proceeds of \$0.4 million from the issuance of 419,065 shares of our common stock at an average price per share, after the applicable discount, of \$1.04.

On February 18, 2009, we completed a financing under the May 2008 CEFF, resulting in proceeds of \$1.0 million from the issuance of 857,356 shares of our common stock at an average price per share, after the applicable discount, of \$1.17.

On March 31, 2009, we completed a financing pursuant to the May 2008 CEFF resulting in gross proceeds of approximately \$1.1 million from the issuance of 1,015,127 shares of our common stock at an average price per share, after the applicable discount, of \$1.08.

On April 8, 2009, we completed a financing pursuant to the December 2008 CEFF resulting in gross proceeds of approximately \$1.0 million from the issuance of 806,457 shares of our common stock at an average price per share, after the applicable discount, of \$1.24.

On May 7, 2009, we completed a financing pursuant to the December 2008 CEFF resulting in gross proceeds of approximately \$1.0 million from the issuance of 1,272,917 shares of our common stock at an average price per share, after the applicable discount, of \$0.79.

Financings Pursuant to Common Stock Offerings

Historically, we have, and expect to continue to, fund our business operations through various sources, including financings pursuant to common stock offerings. We have filed a universal shelf registration statement on Form S-3 (No. 333-151654) (2008 Universal Shelf) with the SEC for the proposed offering from time to time of up to \$150 million of our 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.

Financing under the 2008 Universal Shelf

On May 8, 2009, we entered into definitive agreements with select institutional investors for the purchase of 14 million units of our common stock and warrants to purchase common stock pursuant to a registered direct public offering. The purchase price for each share of common stock and related warrant together is \$0.81 and will result in gross proceeds of approximately \$11.3 million. For each share of common stock purchased, investors will receive warrants to purchase 0.5 shares of common stock at an exercise price of \$1.15 per share. The closing of the offering is expected to take place on May 13, 2009, subject to customary closing conditions. We also entered into a related placement agent agreement (the "Placement Agent Agreement") with Lazard Capital Markets LLC, who is acting as exclusive placement agent for the offering. We have agreed to pay the placement agent an aggregate fee of 6% of the gross proceeds upon the closing of the offering and to reimburse the placement agent for certain expenses incurred by it in connection with the offering. Under the Placement Agent Agreement, we agreed not to draw down on our CEFFs for a period of 30 days after the offering, and, for the 60 days following that date, agreed to an aggregate draw down limit of 2% of our outstanding common stock and have also agreed not to sell, for a period of 90 days following the entry into the definitive agreements, any of our common stock other than in connection with this offering, pursuant to employee benefit plans, or in connection with strategic alliances involving us and a strategic partner. In addition, each of our directors and select executive officers have agreed to certain lock-up provisions with regard to future sales of our common stock for a period of 90 days after the offering. The common stock issued and issuable by exercise of the warrants in connection with this offering are covered by the 2008 Universal Shelf.

Debt

Historically, we have, and expect to continue to, fund our business operations through various sources, including debt arrangements such as credit facilities and equipment financing facilities.

Loan with PharmaBio

We have a loan with PharmaBio with an outstanding principal balance of \$8.5 million, which is due and payable on April 30, 2010, together with interest since October 1, 2006, accrued at the prime rate, compounded annually. See our Annual Report on Form 10-K for the year ended December 21, 2008 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Loan with PharmaBio.” As of March 31, 2009, the outstanding balance under the loan was \$10.2 million (\$8.5 million of pre-restructured principal and \$1.7 million of accrued interest) and was classified as a long-term loan payable on the Consolidated Balance Sheets.

Equipment Financing Facilities

In May 2007, we entered into a Credit and Security Agreement with GE Business Financial Services Inc. (GE, formerly Merrill Lynch Business Financial Services Inc.), as Lender, pursuant to which GE agreed to provide us a \$12.5 million facility (Facility) to fund our capital programs. The right to draw under this Facility expired on November 30, 2008. See our Annual Report on Form 10-K for the year ended December 21, 2008 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Equipment Financing Facilities.” As of March 31, 2009, approximately \$2.2 million was outstanding under the facility (\$1.7 million classified as current liabilities and \$0.5 million as long-term liabilities).

Contractual Obligations and Commitments

During the three month period ended March 31, 2009, there were no material changes to our contractual obligations and commitments disclosures as set forth in 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 – Contractual Obligations”.

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

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.

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

We are not aware of any pending or threatened legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the conduct of our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any 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 future proceeding 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 Annual Report on Form 10-K for the year ended December 31, 2009.

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

Receipt of the Complete Response letter in April 2009 has further delayed the FDA's review of our NDA for Surfaxin for the prevention of RDS in premature infants. In its letter, the FDA focused on whether the BAT can adequately distinguish change in Surfaxin drug product over time and whether we have adequately validated the BAT and determined its final acceptance criteria. We believe that validation of the BAT to the FDA's satisfaction would confirm the comparability of Surfaxin drug product used in the clinical trials to the commercial Surfaxin drug product. We believe that data already submitted to the FDA support the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product and demonstrate that the BAT can adequately distinguish change in Surfaxin over time and is an appropriate test for monitoring Surfaxin biological activity throughout its shelf-life. If we are unable to reach agreement with the FDA, however, the FDA will likely require that we perform further studies or undertake other activities. If the FDA does not agree that we have confirmed the comparability of Surfaxin drug product used in the clinical trials to the commercial Surfaxin drug product, such additional activities could potentially include new clinical trials, in which event we would be unable to gain approval of Surfaxin, if at all, within our anticipated timeline. It is also possible that the FDA may not be satisfied with our responses to the other items that the FDA identified in the Complete Response letter. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to secure 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.

Receipt of the April 2009 Complete Response letter has caused us to reevaluate certain strategies and take additional steps to conserve our financial resources, which may subject us to unanticipated risks and uncertainties.

Following receipt of the Complete Response letter from the FDA, to conserve our cash resources, we implemented cost containment measures and reduced our workforce from 115 to 91 employees. The workforce reduction was focused primarily in our commercial and corporate administrative groups and is expected to result in annual savings of approximately \$2.6 million. We expect to take a one-time charge of approximately \$0.6 million in the second quarter ending June 30, 2009 related to the workforce reduction.

We have retained the core capabilities that we need to support development of our KL₄ surfactant technology, including our quality, manufacturing and research and development resources and continue to make investments in our proprietary KL₄ Surfactant Technology pipeline programs. However, as we continue to manage our cash resources and gain a better understanding of the revised timeline, reductions in investment in research and development programs may cause us to experience additional delays. While we remain reasonably confident that we can achieve our goals within our expected timelines, we will continue to assess our regulatory position as well as 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.

Receipt of the April 2009 Complete Response letter from the FDA has caused us to reassess our plans for commercializing Surfaxin and our other product candidates in the United States, which will subject us to risks and uncertainties.

Prior to receipt of the Complete Response letter, we expected to incur expenses at an annual rate of approximately \$20 - \$25 million to build a fully-integrated pediatric franchise and establish our own specialty pulmonary commercial organization to initially execute the launch of Surfaxin in the United States. We have now re-evaluated this strategy in light of our need to conserve our resources and now believe that it is in our best interest financially to seek strategic alliances or other collaboration arrangements to support development and potential commercialization of Surfaxin, Surfaxin LS and Aerosurf to address a wide range of neonatal and pediatric indications, beginning with RDS. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, potentially, the performance of third-party strategic partners and collaborators with whom we may contract.

As we no longer plan to build our own sales and marketing organization in the United States, we will likely be dependent upon strategic partners and collaborators for the marketing and sales of Surfaxin for the prevention of RDS and for Surfaxin LS and Aerosurf for indications affecting neonatal and pediatric patients. If we are unable to identify strategic partners or do not succeed in entering into these agreements, or if we or our strategic partners and collaborators do not perform under such agreements, it would have a material adverse effect on our ability to commercialize our products. In addition, if we do not succeed in securing marketing and sales capabilities, the commercial launch of our products in the United States may be delayed. If we are successful in entering into strategic alliance agreements or other collaboration arrangements, if we breach or terminate the agreements that make up these arrangements or if our commercialization partners otherwise fail to conduct their activities in a timely manner or if there is a dispute about their respective obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability to commercialize our products in the United States. In addition, we may depend on our partner's expertise and dedication of sufficient resources to commercialize our products in the United States. Moreover, we may, in the future, grant to strategic partners rights to license and commercialize potential products developed under development collaboration agreements. Under such arrangements, our collaboration partners may control key decisions relating to the development of our products. The rights of our partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin, Surfaxin LS and Aerosurf.

In light of the delayed timeline for the anticipated approval for Surfaxin, we will have to raise significant additional capital to continue our existing planned research and development activities and continue to operate as a going concern. Moreover, such additional financing could result in equity dilution.

Until such time as we are able to commercialize our Surfaxin drug product, if approved, and generate revenues, we will need substantial additional funding to conduct our ongoing research and product development activities and continue to operate as a going concern. Our operating plans require that expenditures will only be committed if we achieve important development and regulatory milestones and have the necessary working capital resources. Accordingly, as we attempt to conserve our resources during this period, we may experience additional delays in certain of our development programs. If we are unable to raise substantial additional funds through future debt and equity financings and /or strategic and collaborative arrangements with potential partners, we may be forced to further limit many, if not all, of our programs and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would develop ourselves.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, through future debt and equity financings and /or strategic and collaborative ventures with potential partners, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In addition, if our recent registered direct offering closes as anticipated on May 13, 2009, we will have remaining approximately 300,000 shares of capital stock available for issuance (and not otherwise reserved). Accordingly, we may be unable to undertake additional financings without first seeking stockholder approval, a process that is time consuming and could impair our ability to efficiently raise capital when needed. In that case, we may be forced to further limit development of many, if not all, of our programs and may have to grant development and/or commercialization rights in our products to third parties. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

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 an inability to access the capital markets at a time when we would like or require, and an increased cost of capital. Except for our CEFFs, we currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain, only available on unattractive terms or could 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 common stock on The Nasdaq Global Market. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could require the delay of new product development and clinical trial plans.

To meet our capital requirements, 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 there can be no assurance that we will take any further specific actions or enter into any transactions.

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

During the three months ended March 31, 2009, 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 months ended March 31, 2009.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: May 11, 2009

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

Date: May 11, 2009

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.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery), dated September 18, 2002.	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as filed with the SEC on March 31, 2003.
3.2	Certificate of 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.
3.3	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.
3.4	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, 2005, as filed with the SEC on August 5, 2005.
3.5	Amended and Restated By-Laws of Discovery, as amended effective December 11, 2007.	Incorporated by reference to Exhibit 3.5 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, as filed with the SEC on March 14, 2008.
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 for the quarter ended September 30, 2004, 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.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
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.
4.10	Warrant Agreement dated December 12, 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 December 15, 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: May 11, 2009

/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: May 11, 2009

/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 March 31, 2009 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 11, 2009

/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.