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

FORM 10-Q

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

For the quarterly period ended June 30, 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	**94-3171943**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

(215) 488-9300
(Registrant's telephone number, including area code)

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

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 x
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 x

As of August 6, 2009, 119,790,184 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; the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our KL_4 surfactant technology and our capillary aerosolization technology platform, including planning for and timing of any clinical trials and potential development milestones; the development of financial, clinical, manufacturing and distribution plans related to the potential commercialization of our drug products, if approved; and 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 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:

- risks related generally to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug product candidates that we are developing to address Respiratory Distress Syndrome (RDS) in premature infants including Surfaxin® (lucinactant) for the prevention of RDS, our lyophilized KL_4 surfactant (Surfaxin LS™) and our aerosolized KL_4 surfactant (Aerosurf®);
- the risk that the FDA may require us to conduct additional activities with respect to our fetal rabbit biological activity assay and release test in order to advance our KL_4 surfactant pipeline;
- the risk that we and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;
- 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 preclinical studies and other efforts, and potentially multiple clinical trials, which may be subject to potentially significant delays or regulatory holds, or fail, and which must be conducted using sophisticated and extensive analytical methodologies, including an acceptable biological activity test, if required, as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities;
- risks relating to our ability to develop and manufacture drug products and capillary aerosolization systems for clinical studies and, if approved, for commercialization of 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 product substances, capillary 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, market conditions, the competitive landscape or otherwise may make it difficult to launch and profitably sell our products;
- the risk that we may be unable to identify potential strategic partners or collaborators with whom we can develop and, if approved, commercialize our products in a timely manner, if at all;
- the risk that we or our strategic partners or collaborators will not be able to attract or maintain qualified personnel;
- the risk that we may not be able to raise additional capital or enter into strategic alliances or collaboration agreements (including strategic alliances for development or commercialization of our KL_4 surfactant drug products and combination drug-device products;
- risks that the ongoing credit crisis will adversely affect our ability to fund our activities, that our share price will not regain a level that would permit us to access capital from our Committed Equity Financing Facilities (CEFFs), that the CEFFs may expire before we are able to access the full dollar amount potentially available under the CEFFs, and that additional equity financings could result in substantial 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 Surfactant Replacement Therapies (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
- 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)

	June 30, 2009	December 31, 2008
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 23,377	$ 22,744
Available-for-sale marketable securities	—	2,048
Prepaid expenses and other current assets	247	625
Total Current Assets	23,624	25,417
Property and equipment, net	5,285	5,965
Restricted cash	400	600
Other assets, including deferred financing costs	631	907
Total Assets	$ 29,940	$ 32,889
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,850	$ 2,111
Accrued expenses	4,253	5,313
Loan payable, including accrued interest	10,291	—
Equipment loans, current portion	1,160	2,442
Total Current Liabilities	17,554	9,866
Loan payable, including accrued interest	—	10,128
Equipment loans, non-current portion	714	1,092
Other liabilities	713	870
Total Liabilities	18,981	21,956
Stockholders' Equity:		
Common stock, $0.001 par value; 180,000 shares authorized; 120,103 and 101,588 shares issued; and 119,790 and 101,275 shares outstanding at June 30, 2009 and December 31, 2008, respectively.	120	102
Additional paid-in capital	358,210	341,293
Accumulated deficit	(344,317)	(327,409)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Other comprehensive income	—	1
Total Stockholders' Equity	10,959	10,933
Total Liabilities & Stockholders' Equity	$ 29,940	$ 32,889

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 June 30,		Six Months Ended June 30,	
	2009	**2008**	**2009**	**2008**
Revenue from collaborative arrangement and grants	$ —	$ 2,500	$ —	$ 4,550
Expenses:				
Research and development	5,052	7,439	10,659	14,670
General and administrative	2,592	5,076	5,688	9,582
Total expenses	7,644	12,515	16,347	24,252
Operating loss	(7,644)	(10,015)	(16,347)	(19,702)
Other income / (expense):				
Interest and other income	16	217	21	658
Interest and other expense	(280)	(417)	(582)	(885)
Other income / (expense), net	(264)	(200)	(561)	(227)
Net loss	$ (7,908)	$ (10,215)	$ (16,908)	$ (19,929)
Net loss per common share - Basic and diluted	$ (0.07)	$ (0.11)	$ (0.16)	$ (0.21)
Weighted average number of common shares outstanding - basic and diluted	112,712	96,691	107,433	96,670

See notes to consolidated financial statements

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

	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Cash flows from operating activities:		
Net loss	$ (16,908)	$ (19,929)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,013	1,140
Stock-based compensation and 401(k) match	2,010	2,494
Loss on disposal of property and equipment	—	98
Changes in:		
Receivable from collaborative arrangement	—	(2,500)
Prepaid expenses and other current assets	378	212
Accounts payable	(261)	2,243
Accrued expenses	(1,060)	(2,007)
Other assets	2	2
Other liabilities and accrued interest on loan payable	6	272
Net cash used in operating activities	(14,820)	(17,975)
Cash flows from investing activities:		
Purchase of property and equipment	(59)	(470)
Restricted cash	200	—
Purchases of marketable securities	—	(17,773)
Proceeds from sales or maturity of marketable securities	2,047	27,795
Net cash provided by/(used in) investing activities	2,188	(9,552)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	14,925	8
Proceeds from equipment loans	—	251
Principal payments under equipment loan obligations	(1,660)	(1,422)
Net cash provided by/(used in) financing activities	13,265	(1,163)
Net increase / (decrease) in cash and cash equivalents	633	(9,586)
Cash and cash equivalents - beginning of period	22,744	36,929
Cash and cash equivalents - end of period	$ 23,377	$ 27,343
Supplementary disclosure of cash flows information:		
Interest paid	$ 145	$ 299
Non-cash transactions:		
Unrealized (loss) on marketable securities	(1)	(35)

See notes to consolidated financial statements

Notes to Consolidated Financial Statements (unaudited)

Note 1 – The Company and Basis of Presentation

The Company

Discovery Laboratories, Inc. (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 KL_4 proprietary technology produces a synthetic, peptide-containing surfactant (KL_4 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 KL_4 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 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 KL_4 surfactant technology. On April 17, 2009, we received a Complete Response Letter from the FDA that was primarily focused on our fetal rabbit biological activity test (BAT, one of many analytical Quality Control tests for Surfaxin and our other KL_4 pipeline programs), including whether preclinical data from preterm lamb studies and the BAT had established to the FDA's satisfaction that Surfaxin clinical drug product is comparable to the to-be-manufactured commercial drug product (Comparability). We requested an "end-of-review" meeting with the FDA, which occurred on June 2, 2009. At that meeting, the FDA suggested that, to demonstrate Comparability and increase the likelihood of gaining Surfaxin approval, we could consider conducting a limited clinical trial. We plan to engage the FDA in further discussions to ascertain whether approval can be gained without a potentially lengthy and expensive clinical trial (which we believe is not the best use of our limited resources) or through a limited clinical trial. We also plan to discuss with the FDA our continuing quality improvement initiatives intended to further optimize the BAT. Depending upon the outcome of these interactions with the FDA, we will determine what steps we will take to potentially gain approval of Surfaxin, including, if warranted, exercising our right of appeal through the FDA's Formal Dispute Resolution process.

Our first priority now is to maximize the inherent value in our KL_4 surfactant technology by focusing on our novel lyophilized and aerosolized KL_4 surfactant pipeline programs to address the most significant respiratory conditions affecting pediatric populations. We believe that we will be able to use the established proof-of-efficacy of Surfaxin in RDS to minimize development risk in these programs and potentially greatly improve the management of RDS while expanding the use of surfactants to treat significantly more patients. Our lyophilized KL_4 surfactant, beginning with Surfaxin LS, is manufactured as a dry powder formulation and reconstituted as a liquid prior to use. It also potentially may support future development of our pipeline of KL_4 surfactant-based therapies. Aerosurf is our proprietary KL_4 surfactant in aerosolized form, which we are developing using our proprietary Capillary Aerosolization Technology initially to treat premature infants at risk for RDS. Premature infants with RDS currently 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. If approved, Aerosurf will make it 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.

We are actively assessing various strategic and financial alternatives to secure necessary capital and advance our KL_4 respiratory pipeline programs to maximize shareholder value. We are focused on accomplishing our objectives through strategic alliances. Although we are presently actively engaged in discussions regarding several potential strategic alliances, there can be no assurance that any such strategic alliance or other financing alternatives can be successfully concluded.

Over time, we plan to develop our KL_4 surfactant technology into a robust pipeline of products that potentially will 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 addition, we are conducting research and development with our KL_4 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 and six months ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. 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 financing 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, if approved.

Following receipt of the April 2009 FDA Complete Response Letter for Surfaxin, and after the June 2, 2009 meeting with the FDA, we have made fundamental changes in our business strategy. We are actively assessing various strategic and financial alternatives to secure necessary capital and advance its KL_4 respiratory pipeline programs to maximize shareholder value. We are focused on accomplishing our objectives through strategic alliances. Although we are presently actively engaged in discussions regarding several potential strategic alliances, there can be no assurance that any such strategic alliance or other financing alternatives can be successfully concluded.

Our capital requirements will depend upon many factors, including the success of our product development and commercialization plans. Currently, we are focused on developing our lead KL_4 surfactant products, Surfaxin LS, Aerosurf and Surfaxin, 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 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.

In April and May 2009, we completed two draw downs under our December 2008 CEFF and raised an additional $2.0 million. In addition, on May 13, 2009, we completed a registered direct public offering resulting in gross proceeds of $11.3 million ($10.5 million net). As of June 30, 2009, we had cash and marketable securities of $23.4 million. Under our two CEFFs, we potentially may raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of $75.3 million. However, as of August 6, 2009, neither CEFF was available because our stock price was below the minimum price required to utilize the CEFFs. A third CEFF expired on May 12, 2009. Also, as of June 30, 2009, our $10.3 million loan with Novaquest is classified as a current liability, payable in April 2010. *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 a Complete Response letter for Surfaxin that we received from the FDA in April 2009, 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 KL_4 surfactant technology, including our quality, manufacturing and research and development resources. We incurred a one-time charge of approximately $0.6 million in the quarter ending June 30, 2009 related to the workforce reduction (*see* Note 5 - Commercial Strategy and Cost Containment Measures).

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 strategic and collaborative ventures with potential partners and/or future debt and equity financings, 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, as of June 30, 2009, we have authorized capital available for issuance (and not otherwise reserved) of approximately 300,000 shares of common stock. 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. 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. As of June 30, 2009 and 2008, 31.4 million and 21.1 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 and six months ended June 30, 2009 and 2008 are as follows:

(in thousands)	For the three months ended June 30,		For the six months ended June 30,	
	2009	2008	2009	2008
Net loss	$ (7,908)	$ (10,215)	$ (16,908)	$ (19,929)
Change in unrealized (losses)/gains on marketable securities	—	(84)	(1)	(35)
Comprehensive loss	$ (7,908)	$ (10,299)	$ (16,909)	$ (19,964)

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 and six months ended June 30, 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 – Commercial Strategy and Cost Containment Measures

In April 2009, following receipt of the Complete Response letter, we reviewed all aspects of our business with an immediate intention to conserve cash. We re-evaluated our plans to establish our own specialty pulmonary organization to commercialize our potential pediatric products 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.

In addition, we implemented cost containment measures and reduced our workforce from 115 to 91 employees, focused primarily on commercial and corporate personnel. We have retained our core capabilities to support development of our KL_4 surfactant technology, including quality, manufacturing and research and development resources. We incurred a charge of $0.6 million in the second quarter of 2009 associated with staff reductions and the close-out of certain contractual arrangements, which was accounted for in accordance with Statement of Financial Accounting Standards No. 146 *"Accounting for Costs Associated with Exit or Disposal Activities"* and is included within the appropriate line items on the Statement of Operations ($0.4 million in general and administrative expenses and $0.2 million in research and development expenses). As of June 30, 2009, payments totaling $0.4 million had been made related to these items and $0.2 million were unpaid.

(in thousands)	Severance and Benefits Related	Termination of Commercial Programs	Total
Q2 2009 Charge	$ 554	$ 74	$ 628
Payments / Adjustments	(450)	—	(450)
Liability as of June 30, 2009	$ 104	$ 74	$ 178

Note 6 – Stockholders' Equity

May 2009 Registered Direct Public Offering

On May 13, 2009, we completed a registered direct public offering that resulted in gross proceeds of $11.3 million ($10.5 million net proceeds) from the issuance of 14.0 million shares of our common stock and warrants for seven million shares of common stock. The shares were sold to select institutional investors at a price of $0.81 for each share of common stock, together with a related warrant to purchase 0.5 shares of common stock. The warrants are exercisable for a period of five years at an exercise price of $1.15 per share. Lazard Capital Markets LLC, acted as the exclusive placement agent for the offering and received a fee of 6% of the gross proceeds of the offering and reimbursement of 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 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 the 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 agreed to certain lock-up provisions with regard to future sales of our common stock for a period of 90 days after the offering. All lock-up provisions expire on August 16, 2009. The common stock issued and issuable by exercise of the warrants in connection with this offering are covered by the universal shelf registration statement on Form S-3 (No. 333-151654) (2008 Universal Shelf).

Committed Equity Financing Facilities

As of June 30, 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 expired on May 12, 2009. Under the December 2008 CEFF, as of June 30, 2009, we had 12.9 million shares potentially available for issuance (up to a maximum of $23.0 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 June 30, 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 and if our stock price regains a level above the CEFF minimum price requirement, to support our working capital needs and maintain cash availability in 2009.

Financings pursuant to the CEFF

On January 2, 2009, we completed a financing that was initiated in 2008 under the May 2008 CEFF, resulting in gross 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 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 under 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 under 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 under 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 under 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 7 – Fair Value Measurements

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

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

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

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

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 June 30, 2009.

	Fair Value	Fair value measurement using		
Assets	June 30, 2009	Level 1	Level 2	Level 3
Money Markets and Certificates of Deposit	$ 21,690	$ 21,690	$ -	$ -
Restricted Cash	600	600	-	-
Total	$ 22,290	$ 22,290	$ -	$ -

Note 8 – 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:

	June 30, 2009	June 30, 2008
Expected volatility	92%	77%
Expected term	4 and 5 years	4 and 5 years
Risk-free interest rate	1.17% - 1.35%	3.5%
Expected dividends	–	–

The total employee stock-based compensation for the three and six months ended June 30, 2009 and 2008 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Research & Development	$ 242	$ 359	$ 445	$ 691
General & Administrative	721	824	1,368	1,547
Total	$ 963	$ 1,183	$ 1,813	$ 2,238

As of June 30, 2009, there was $4.1 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 1.8 years.

Note 9 – Subsequent Events

Results of June 2nd Meeting with FDA

On July 1, 2009, after receipt of written minutes from the FDA, we announced the results of our June 2, 2009 meeting with the FDA. We had requested this meeting after receiving the FDA's April 17 Complete Response Letter for Surfaxin for the purpose of discussing resolution of the remaining primary issue necessary for approval of Surfaxin. The meeting focused primarily on certain aspects of a Surfaxin fetal rabbit biological activity test (BAT), a quality control stability and release test, and (i) whether data that we had previously submitted to the FDA and generated using both a well-established preterm lamb model of RDS and the BAT adequately demonstrates comparability between Surfaxin drug product used in Phase 3 clinical trials and Surfaxin drug product intended to be manufactured for commercial use ("Comparability"), and (ii) whether the BAT can adequately distinguish change in Surfaxin biological activity over time.

At the meeting, we presented a compilation of previously-submitted data from the preterm lamb model and BAT studies, together with a comprehensive statistical evaluation of that data (in the form of a comparative regression analysis) that was intended to establish Comparability. The FDA stated, for the first time, that, instead of applying comparative regression analysis, it would require that data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. Taking this newly-defined standard into account, we now believe it unlikely that we can establish Comparability with existing preclinical data and gain Surfaxin approval in the near term. *See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview – Research and Development Update – Surfaxin® for the Prevention of Respiratory Distress Syndrome in Premature Infants."

As a result of these developments, we have made fundamental changes in our business strategy. To secure capital and advance our KL_4 surfactant pipeline programs, we are seeking to reduce our financial burden by entering into strategic alliances in all markets, including, the United States. We plan to focus on maximizing the inherent value of our novel KL4 surfactant and aerosolization platforms. Our highest-priority pipeline programs are Surfaxin LS and Aerosurf, which we believe have the potential to greatly advance the management of RDS and treat more patients suffering from RDS, while creating a significant economic opportunity. *See* "Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview – Business Strategy Update."

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 KL_4 proprietary technology produces a synthetic, peptide-containing surfactant (KL_4 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 KL_4 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 LS™, Aerosurf®, and Surfaxin®, to address the most significant respiratory conditions affecting pediatric populations. In connection with our New Drug Application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, on April 17, 2009, we received a Complete Response letter from the U.S. Food and Drug Administration (FDA). (*See* "Surfaxin® for the Prevention of Respiratory Distress Syndrome in Premature Infants," below). If approved, Surfaxin will represent the first synthetic, peptide-containing surfactant approved for use in pediatric medicine. Our lyophilized KL_4 surfactant, beginning with Surfaxin LS, is manufactured as a dry powder formulation and reconstituted as a liquid prior to use. It potentially may support future development of our pipeline of KL_4 surfactant-based therapies. Aerosurf is our proprietary KL_4 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 currently 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. If approved, Aerosurf will make it 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.

We are actively assessing various strategic and financial alternatives to secure necessary capital and advance our KL_4 respiratory pipeline programs to maximize shareholder value. We are focused on accomplishing our objectives through strategic alliances. Although we are presently actively engaged in discussions regarding several potential strategic alliances, there can be no assurance that any such strategic alliance or other financing alternatives can be successfully concluded.

Over time, we plan to develop our KL_4 surfactant technology into a robust pipeline of products that potentially will 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. In addition, we are conducting research and development with our KL_4 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

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 April 2009 FDA Complete Response Letter for Surfaxin, and after the June 2, 2009 meeting with the FDA, we have made fundamental changes in our business strategy. To secure capital and advance our KL_4 surfactant pipeline programs, we are seeking to reduce our financial burden by entering into strategic alliances in all markets, including the United States.

- Accordingly, we are now seeking alliances that potentially provide non-dilutive capital in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses, and that leverage the individual expertise and capabilities of the parties. This change has resulted in an increase in interest among potential partners and we are now actively in discussions with certain interested parties. In addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements, including potentially satisfying our loan with Novaquest, and continue our operations. Although we are hopeful that we can achieve one or more strategic alliances in our key target markets, there can be no assurance that any such strategic alliance or any alternative financing will be achieved.

- In addition, to conserve our cash resources, in April 2009, 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 incurred a one-time charge of $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 KL_4 surfactant technology, including our quality, manufacturing and research and development resources and continue to make investments in our proprietary KL_4 surfactant technology pipeline programs

- To advance our KL4 pipeline products, we plan to make prudent investments in preclinical studies and our drug product and device development programs, and will focus our resources on being in a position to initiate key clinical programs after we have secured appropriate strategic alliances and necessary capital. Our preparatory work is expected to include, where appropriate, discussions with U.S. and European regulatory authorities to gain information about the requirements for our regulatory packages and other planning activities required for the initiation of our planned clinical trials.

As of June 30, 2009, we had cash and marketable securities of $23.4 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 $75.3 million. A third CEFF expired on May 12, 2009. (*See* "Liquidity and Capital Resources – Committed Equity Financing Facilities," and "– Financings Pursuant to Common Stock Offerings"). Our capital requirements depend upon many factors, including the success of our product development and commercialization plans. Also, as of June 30, 2009, our $10.3 million loan with Novaquest is classified as a current liability, payable in April 2010. We are currently focused on developing our lead KL_4 surfactant products, Surfaxin LS, Aerosurf and Surfaxin, 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 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. To secure capital and advance our KL_4 surfactant pipeline programs, our top priority is to enter into strategic alliances in all markets, including, the United States. In addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements and continue our operations. 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.

Our Potential Market Opportunities

Surfactants today are approved solely to address RDS in premature infants and we believe the current market is underserved and constrained by limitations associated with the currently-approved animal-derived products. The annual revenue from the current surfactant market is estimated to be approximately $200 million worldwide (IMS Midas Data MAT, September 2008); however, we do not believe that this revenue value is indicative of our RDS revenue opportunity. With our synthetic KL_4 surfactant and Capillary Aerosolization Technology platform, over time, we plan to potentially displace the animal-derived surfactants and treat many more of the premature infants that currently are not treated with surfactant therapy today.

Surfaxin LS™, a lyophilized (dry powder) formulation of Surfaxin, is administered in the same manner as Surfaxin and the currently-approved animal-derived surfactants. However, Surfaxin LS is handled more conveniently than both Surfaxin and the currently-approved animal-derived surfactants and exhibits characteristics that may further improve its clinical performance. We believe that the potential advantages and benefits of Surfaxin LS may support a market penetration and a significant price premium relative to today's standard of care and could, over time, create a potential worldwide annual market opportunity of up to $250 million.

To avoid the risks associated with surfactant administration, which requires invasive intubation and mechanical ventilation, neonatologists generally prefer to treat RDS-diagnosed infants with nasal continuous positive air pressure (nCPAP). Approximately 240,000 low birth weight infants are managed on nCPAP in the U. S. annually (Vermont Oxford Network Data, 2005/2006 (VON Data)). nCPAP may fail in more than 50% (depending on gestational age, VON Data) of these infants, who will require subsequent intubation and surfactant therapy, resulting in delayed surfactant therapy and potentially less favorable clinical outcomes (Soll, Cochrane Database of Systematic Reviews, 1997, Issue 4). As a result, of the more than 500,000 patients at-risk for developing RDS in developed markets worldwide, less than 200,000 are treated with surfactant therapy today, including approximately 80,000 in the United States (VON Data, CDC National Vital Statistics, 2005, UNICEF Online Data Set, 2005).

Aerosurf® is a drug-device combination product that delivers our KL_4 surfactant in aerosolized form via nCPAP. As less invasive nCPAP is the preferred method of treating RDS infants, the combination of Aerosurf, if approved, and nCPAP will make it possible to deliver surfactant therapy to many more premature infants than are treated currently, potentially significantly expanding the treated-patient population. In addition, because Aerosurf has the potential to reduce the need for mechanical ventilation, the cost of which can exceed $25,000 per patient (ZD Associates Primary Market Research, 2009; Gdovin, *J Peds Pharm & Therapuetics*, 2006), we believe that we will be able to establish a new frame of reference for pricing and command a significant price premium for this novel product based on hospital cost-savings (i.e., average days of mechanical ventilation avoided and reduction in related morbidities). As such, we believe that the potential advantages and benefits of Aerosurf may, over time, support a potential worldwide annual RDS market opportunity approaching $750 million.

As a result, we believe that the combined revenues from Surfaxin LS and Aerosurf have the potential to approach $1 billion for the worldwide annual RDS market opportunity alone.

Surfaxin LS and Aerosurf are investigational drugs currently under development and are subject to all of the risks and uncertainties associated with development-stage drug product candidates, including whether regulatory development and marketing approvals can be successfully obtained. Examples of these and other risks and uncertainties are included in our Annual Report for the year ended December 31, 2008, as amended, and in this Quarterly Report on Form 10-Q, as well as in our other filings with the Securities and Exchange Commission including, without limitation, the most recent reports on Form and 8-K.

Research and Development Update – KL_4 Surfactant Pipeline Programs

Our first priority is to maximize the inherent value in our KL_4 surfactant technology by focusing on our novel lyophilized and aerosolized KL_4 surfactant pipeline programs to address the most significant respiratory conditions affecting pediatric populations, beginning with RDS. We believe that we will be able to use the established proof-of-efficacy of Surfaxin to minimize development risk in these programs and potentially greatly improve the management of RDS while expanding the use of surfactants to treat significantly more patients.

Programs Addressing Respiratory Distress Syndrome (RDS)

RDS is one of the most common, potentially life-threatening disorders, with more than 500,000 low-birth-weight premature infants at risk globally each year. However, fewer than 200,000 infants per year now receive surfactant therapy (with animal-derived surfactants) (Von Data) because healthcare practitioners try to avoid the risks associated with intubation and mechanical ventilation, which are presently required for surfactant administration. (*See* "Overview – Business Strategy Update – *Our Potential Market Opportunities*"). If the risk of intubation and mechanical ventilation could be reduced or eliminated, the surfactant-eligible RDS patient population could be significantly expanded. Our advanced-stage RDS programs include:

Surfaxin LS™

Surfaxin LS is a lyophilized (dry powder) formulation of KL_4 surfactant that is reconstituted to a liquid immediately prior to administration. This formulation is intended to improve product flexibility and ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and exhibits characteristics that may further improve product clinical performance. We are presently conducting preclinical studies and preparing for a Phase 2/3 clinical global registration program. We plan to engage U.S. and European regulatory authorities this year and anticipate initiating a clinical program after we have secured appropriate strategic alliances and necessary capital.

Aerosurf®

Aerosurf is KL_4 surfactant in aerosolized form using our proprietary Capillary Aerosolization Technology. Presently, surfactant treatment for neonatal RDS requires administration through an endotracheal tube and, although life-saving, the invasiveness of this method often results in serious respiratory conditions and complications. Aerosurf, if approved, holds the promise to significantly expand the use of KL_4 surfactant therapy by providing neonatologists with a novel means of administration without invasive endotracheal intubation and mechanical ventilation. Pending Surfaxin approval, we had curtailed significant investments in research, engineering, device development and device manufacturing capabilities as well as our next-generation capillary aerosolization system. However, we continue to conduct certain developmental and preclinical activities to support our regulatory package. We have met with and received guidance from the FDA with respect to the design of our planned Phase 2 clinical program. We expect to accelerate investment in our Capillary Aerosolization Technology and potentially initiate a Phase 2 clinical program after we have secured appropriate strategic alliances and necessary capital.

Surfaxin® for the Prevention of Respiratory Distress Syndrome in Premature Infants

In connection with our NDA for Surfaxin, our first product based on our novel KL_4 surfactant technology, on April 17, 2009, we received a Complete Response letter from the FDA that focused primarily on certain aspects of a Surfaxin fetal rabbit biological activity test (BAT), a quality control stability and release test, and (a) whether data that we had previously submitted to the FDA and generated using both a well-established preterm lamb model of RDS and the BAT adequately demonstrates comparability between Surfaxin drug product used in Phase 3 clinical trials and Surfaxin drug product intended to be manufactured for commercial use (“Comparability”), and (b) whether the BAT can adequately distinguish change in Surfaxin biological activity over time. The Complete Response letter also included, among other things, (i) a request to tighten one drug product specification, which we can readily implement, (ii) routine requests to update safety and other information in the NDA, and (iii) information requests about certain regulatory matters. In addition, the FDA indicated that it has approved the trade name Surfaxin. Following receipt of the Complete Response Letter, we requested an “end-of-review” meeting with the FDA, which occurred on June 2, 2009.

At the June 2, 2009 meeting, we presented a compilation of previously-submitted data from the preterm lamb model and BAT studies, together with a comprehensive statistical evaluation of that data (in the form of a comparative regression analysis) that was intended to establish Comparability. The FDA stated, for the first time, that an agreement that it had reached with us in 2006 and 2008 to allow for Comparability to be established using the preterm lamb and BAT studies was unprecedented. The FDA also indicated that, instead of accepting our comparative regression analysis, it would require that data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. Taking this newly-defined standard into account and the expected variability inherent in animal models, we now believe it unlikely that we can establish Comparability with existing preclinical data and gain Surfaxin approval in the near term.

In addition, at the June 2 meeting, with respect to the BAT, (a) the FDA commented that the data presented appears to confirm that the BAT can distinguish active from inactive drug product, and (b) to respond to the FDA’s concern about whether the BAT can adequately distinguish change in Surfaxin biological activity over time, we advised the FDA of ongoing efforts to further refine the BAT in accordance with our continuing quality improvement initiatives. We believe that the BAT, as an ICH validated method, represents an acceptable quality control test to assess biological activity and are continuing to employ the BAT during the conduct of ongoing clinical trials addressing Acute Respiratory Failure and Cystic Fibrosis, consistent with guidance from the FDA, and plan to use the BAT in our pending clinical programs, Surfaxin LS and Aerosurf for RDS.

As an alternative to demonstrating Comparability with preclinical data from the preterm lamb model and the BAT, the FDA suggested that we could consider conducting a limited clinical trial employing only the BAT as a path forward to Surfaxin approval. The FDA suggested that the comparability studies in the preterm lamb model and the BAT would not be necessary if the BAT had been implemented to assess Surfaxin drug product used in the Phase 3 clinical trials. Given our strategic and financial priorities, we believe that it would be more prudent to focus resources on the ongoing lyophilized and aerosolized surfactant development programs rather than conduct a potentially lengthy and costly Surfaxin clinical trial. We nevertheless plan to engage the FDA in further discussions to ascertain whether Surfaxin approval can be gained without an additional clinical trial or through only a limited clinical trial experience. We also plan to discuss with the FDA our continuing quality improvement initiatives intended to further optimize the BAT. Depending upon the outcome of these interactions with the FDA, we will determine what steps we will take to potentially gain approval of Surfaxin, including, if warranted, exercising our right of appeal through the FDA's Formal Dispute Resolution process.

Our Other KL_4 Surfactant Programs

We believe that our KL_4 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.

Acute Respiratory Failure (ARF) and Acute Lung Injury (ALI)

ARF and ALI are severe respiratory conditions associated with prolonged critical care intervention, including mechanical ventilation. Both of these serious medical conditions entail severe surfactant dysfunction. No medications are currently approved for these debilitating conditions.

ARF typically occurs following a serious respiratory infection, such as influenza or respiratory syncytial virus (RSV). We are conducting a Phase 2 ARF clinical trial to determine whether Surfaxin improves lung function and reduces duration of mechanical ventilation in children diagnosed with ARF following a viral infection. Presently, enrollment is approximately 75% complete and the Company believes enrollment will be completed in the first quarter of 2010, with top-line results becoming available shortly thereafter.

ALI is typically associated with severe respiratory infections, certain major surgeries, and lung injury including mechanical ventilator induced lung injury. Together with a leading academic center, we are presently conducting a preclinical assessment to determine the potential utility of aerosolized KL_4 surfactant in the prevention and treatment of ALI.

In addition, hospitalization for influenza and other viral infections, including the pandemic H1N1 virus, is associated with high mortality, morbidity and significant healthcare cost. We believe that our KL_4 surfactant technology may provide a novel solution for patients that require critical care intervention following exposure to viral pathogens. We have held exploratory meetings with U.S. Government officials to explore whether funding can be obtained to accelerate development of these programs in light of concerns regarding pandemic risk. Although we believe that our KL_4 technology may represent a promising alternative, there can be no assurance that any such program will be initiated or that any governmental funding will be obtained.

Cystic Fibrosis (CF)

CF is characterized by a genetic mutation that results in the production of thick, viscous mucus that is difficult to clear from the airways and typically leads to life-threatening respiratory infections. Preclinical and exploratory clinical studies suggest that therapeutic surfactants may improve lung function by loosening mucus and making it easier to clear. Aerosolized KL_4 surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial in CF patients. The trial is being conducted at The University of North Carolina and is funded primarily through a grant provided by the Cystic Fibrosis Foundation. The trial has been designed to assess the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL_4 surfactant in CF patients. The results from this trial are anticipated in first quarter 2010.

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 and six months ended June 30, 2009 was $7.9 million (or $0.07 per share) and $16.9 million (or $0.16 per share), respectively. The net loss for the three and six months ended June 30, 2008 were $10.2 million (or $0.11 per share) and $19.9 million (or $0.21 per share), respectively

Revenue from Collaborative Arrangements and Grants

We did not earn any revenue during the three and six months ended June 30, 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 and six months ended June 30, 2009 were $5.1 million and $10.7 million, respectively. Research and development expenses for the three and six months ended June 30, 2008 were $7.4 million and $14.7 million, respectively. These costs are charged to operations as incurred and are tracked by category, as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
Research and Development Expenses:	**2009**	**2008**	**2009**	**2008**
Manufacturing development	$ 2,772	$ 5,004	$ 6,259	$ 9,370
Development operations	1,412	1,876	2,803	3,991
Direct preclinical and clinical programs	868	559	1,597	1,309
Total Research & Development Expenses	$ 5,052	$ 7,439	$ 10,659	$ 14,670

(1) Included in research and development expenses are charges associated with stock-based employee compensation in accordance with the provisions of FASB Statement of Financial Accounting Standards No. 123R (SFAS No. 123R). For the three and six months ended June 30, 2009, these charges were $0.2 million and $0.4 million, respectively. For the three and six months ended June 30, 2008, these charges were $0.4 million and $0.7 million, respectively.

The decrease in research and development expenses for the three and six months ended June 30, 2009 compared to the same periods 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 KL_4 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 KL_4 surfactant.

The decrease in manufacturing development expenses of approximately $2.2 million and $3.1 million for the three and six months ended June 30, 2009, as compared to the same periods in 2008, is primarily due to: (i) expenditures in the first half 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; (ii) expenditures in the first half of 2008 for the design, development and manufacture of the initial prototype version of our novel capillary aerosolization systems to be used in our anticipated Phase 2 clinical trials; and (iii) a reduction in expenditures related to our efforts in the first half 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 associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R. For the three and six months ended June 30, 2009, these charges were $0.1 million and $0.3 million, respectively. For the three and six months ended June 30, 2008, these charges were $0.2 million and $0.4 million, 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 KL_4 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 in development operations expenses of approximately $0.5 million and $1.2 million for the three and six months ended June 30, 2009, as compared to the same period in 2008, is primarily due to (i) expenditures in the first half 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 half 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 associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R. For the three and six months ended June 30, 2009, these charges were $0.1 million and $0.1 million, respectively. For the three and six months ended June 30, 2008, these charges were $0.2 million and $0.3 million, respectively.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) preclinical activities, including toxicology studies and other preclinical 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 preclinical and clinical programs expenses for the three and six months ended June 30, 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) preclinical activities and product characterization testing of our lyophilized form of Surfaxin; and (iii) preclinical and preparatory activities for anticipated Phase 2 clinical trials for Aerosurf for RDS in premature infants.

Direct preclinical and clinical programs expenses for the three and six months ended June 30, 2008 primarily included: (i) activities associated with the Phase 2 clinical trial of Surfaxin for children with ARF; and (ii) preclinical activities for our Aerosurf program.

In an effort to conserve resources, we plan to continue limiting our investments in preclinical and clinical programs until we have secured appropriate strategic alliances and necessary capital. Where appropriate, we will seek to engage U.S. and European regulatory authorities to gain information about the requirements for our regulatory packages and activities to prepare for planned clinical trials.

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 and six months ended June 30, 2009 were $2.6 million and $5.7 million, respectively. General and administrative expenses for the three and six months ended June 30, 2008 were $5.1 million and $9.6 million respectively. General and administrative expenses for the second quarter of 2009 included $0.4 million of the $0.6 million one-time charge of associated with certain cost containment measures and the workforce reduction following receipt of the Complete Response letter in April 2009. *See* Commercial Strategy and Cost Containment Measures below. Additionally, general and administrative expenses included charges associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123R. For the three and six months ended June 30, 2009, these charges were $0.7 million and $1.4 million, respectively. For the three and six months ended June 30, 2008, these charges were $0.8 million and $1.5 million, respectively.

The decrease of approximately $2.5 million and $3.9 million in general and administrative expenses for the three and six months ended June 30, 2009, as compared to the same periods in 2008, is primarily due to pre-launch commercial activities in the first half of 2008 in anticipation of the potential approval and commercial launch of Surfaxin in May 2008. Following receipt of an Approvable Letter in May 2008, we scaled back our pre-launch commercial activities, although we continued to make limited investments in our commercial capabilities. Accordingly, throughout the remainder of 2008 and the first half 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.

Commercial Strategy and Cost Containment Measures

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. Rather than incur the significant expense that strategy would require, 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 have incurred a one-time charge of $0.6 million ($0.4 million in general and administrative expenses and $0.2 million in research and development expenses) in the second quarter ending June 30, 2009 related to the workforce reduction.

Other Income and (Expense)

Other income and (expense) for the three and six months ended June 30, 2009 were $(0.3) million and $(0.6) million, respectively. Other income and (expense) for the three and six months ended June 30, 2008 were $(0.2) million and $(0.2) million, respectively.

(Dollars in thousands)	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Interest income	$ 16	$ 217	$ 21	$ 653
Interest expense	280	417	582	885
Other income / (expense)	-	—	—	5
Other income / (expense), net	$ (264)	$ (200)	$ (561)	$ (227)

Interest income consists of interest earned on our cash and marketable securities. During the second half of 2008, we transferred 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 2.1% in the first half of 2008 to approximately 0.12% in the first half of 2009. Additionally, our average cash and marketable securities balance declined from $43.2 million in the first half of 2008 to $24.1 million in the first half 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 and six months ended June 30, 2009 as compared to the same periods 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 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. We are actively assessing various strategic and financial alternatives to secure necessary capital and advance its KL_4 respiratory pipeline programs to maximize shareholder value. We are focused on accomplishing our objectives through strategic alliances. Although we are presently actively engaged in discussions regarding several potential strategic alliances, there can be no assurance that any such strategic alliance or other financing alternatives can be successfully concluded.

As of June 30, 2009, we had $10.3 million outstanding under our loan with Novaquest, a strategic investment group of Quintiles Transnational Corp. The outstanding principal and all accrued interest on this loan is due and payable on April 30, 2010. We are pursuing restructuring the terms of this loan with Novaquest and assessing alternative means of financing its payment; however, there can be no assurance that any such restructuring will occur or financing alternatives will be obtained.

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 KL_4 surfactant products, Surfaxin LS, Aerosurf and Surfaxin, 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 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.

In April and May 2009, we completed two draw downs under our December 2008 CEFF and raised an additional $2.0 million. In addition, on May 13, 2009, we completed a registered direct public offering resulting in gross proceeds of $11.3 million ($10.6 million net). As of June 30, 2009, we had cash and marketable securities of $23.4 million. Under our two CEFFs, we potentially may raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of $75.3 million. However, as of August 6, 2009, neither CEFF was available because our stock price was below the minimum price required to utilize the CEFFs. A third CEFF expired on May 12, 2009. *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 Surfaxin Complete Response letter from the FDA in April 2009, 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 KL_4 surfactant technology, including our quality, manufacturing and research and development resources. We incurred a one-time charge of approximately $0.6 million in the 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 strategic and collaborative ventures with potential partners and/or future debt and equity financings, 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, as of June 30, 2009, we have authorized capital available for issuance (and not otherwise reserved) of approximately 300,000 shares of common stock. 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. 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.

In addition to multiple strategic alternatives, including, but not limited to potential business alliances, commercial and development partnerships, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements, including potentially satisfying our loan with Novaquest, and continue our operations. Although we are hopeful that we can achieve one or more strategic alliances in our key target markets, there can be no assurance that any such strategic alliance or any alternative financing will be achieved.

Cash Flows

We had cash, cash equivalents and marketable securities of $23.4 million as of June 30, 2009 as compared to $24.8 million as of December 31, 2008, a decrease of $1.4 million. The decrease is primarily due to $14.7 million used for operating activities and $1.7 million used for debt service, offset by net proceeds of $10.5 million received from the May 2009 financing from the issuance of 14.0 million shares of common stock and $4.5 million received from the issuance of 4.4 million shares of common stock pursuant to financings under our CEFFs.

Cash Flows Used in Operating Activities

Cash flows used in operating activities were $14.7 million and $18.0 million for the six months ended June 30, 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 $0.5 million for the six months ended June 30, 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 $13.3 million and $(1.2) million for the six months ended June 30, 2009 and 2008, respectively.

Cash flows from financing activities for the six months ended June 30, 2009 included net proceeds of $10.5 million from the May 2009 registered direct offering and $4.5 million from financings pursuant to our CEFFs, offset by principal payments on our equipment loan facilities of $1.6 million. Cash flows used in financing activities for the six months ended June 30, 2008 included $0.3 million of proceeds from our equipment financing facilities, offset by $1.4 million of debt service payments under our equipment loan.

Committed Equity Financing Facilities (CEFFs)

As of June 30, 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 expired on May 12, 2009. As of August 6, 2009, neither CEFF was available because our stock price was below the minimum price required to utilize the CEFFs.

Under the December 2008 CEFF, as of June 30, 2009, we had 12.9 million shares potentially available for issuance (up to a maximum of $23.0 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 June 30, 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 and if our stock price regains a level above the CEFF minimum price requirement, 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 that we may continue to, fund our business operations through various sources, including financings pursuant to common stock offerings. We 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 13, 2009, we completed a registered direct public offering that resulted in gross proceeds of $11.3 million ($10.5 million net proceeds) from the issuance of 14.0 million shares of our common stock and warrants for seven million shares of common stock. The shares were sold to select institutional investors at a price of $0.81 for each share of common stock, together with a related warrant to purchase 0.5 shares of common stock. The warrants are exercisable for a period of five years at an exercise price of $1.15 per share. Lazard Capital Markets LLC, acted as the exclusive placement agent for the offering and received a fee of 6% of the gross proceeds of the offering and reimbursement of 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 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 the 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 agreed to certain lock-up provisions with regard to future sales of our common stock for a period of 90 days after the offering. All lock-up provisions expire on August 16, 2009. The common stock issued and issuable by exercise of the warrants in connection with this offering are covered by the 2008 Universal Shelf.

As of June 30, 2009, there was $138.7 million remaining available under the 2008 Universal Shelf for potential future offerings.

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 Novaquest

We have a loan with Novaquest (formerly PharmaBio Development, Inc.), a Strategic Investment Group of Quintiles Transnational Corp., 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." We may repay the loan, in whole or in part, at any time without prepayment penalty or premium. In addition, our obligations to PharmaBio under the loan documents are secured by an interest in substantially all of our assets, subject to limited exceptions set forth in the security agreement. As of June 30, 2009, the outstanding balance under the loan was $10.3 million ($8.5 million of pre-restructured principal and $1.8 million of accrued interest) and was classified as a short-term loan payable (current liability) on the Consolidated Balance Sheets. We are pursuing with Novaquest a potential restructuring of the terms of this loan and are also assessing alternative means of financing its payment, although there can be no assurance that any such restructuring will occur or that financing alternatives will be obtained.

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 June 30, 2009, approximately $1.4 million was outstanding under the facility ($1.1 million classified as current liabilities and $0.3 million as long-term liabilities).

Contractual Obligations and Commitments

During the six month period ended June 30, 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.

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. *See* "Management's Discussion and Analysis of Financial condition and Results of Operations – Overview– Business Strategy Update." In its letter, the FDA focused primarily on certain aspects of a Surfaxin fetal rabbit biological activity test (BAT). We believe that data already submitted to the FDA were sufficient to respond to the issues raised by the FDA about the BAT and, at the June 2, 2009 meeting, presented a compilation of the previously-submitted data from preterm lamb model and BAT studies, together with a comprehensive statistical evaluation of that data (in the form of a comparative regression analysis). However, the FDA indicated that, instead of accepting our comparative regression analysis, it would require that data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. Taking this newly-defined standard into account and the expected variability inherent in animal models, we now believe it unlikely that we can rely upon existing preclinical data and gain Surfaxin approval in the near term.

As an alternative to using preclinical data to gain approval of Surfaxin, the FDA suggested that we could consider conducting a limited clinical trial employing only the BAT as a path forward to Surfaxin approval. Given our strategic and financial priorities, we believe that it would be more prudent to focus resources on the ongoing lyophilized and aerosolized surfactant development programs. We nevertheless plan to engage the FDA in further discussions to ascertain whether Surfaxin approval can be gained without apotentialy lengthy and expensive clinical trial (which we believe is not the best use of our limited resources) or through a limited clinical trial. We also plan to discuss with the FDA our continuing quality improvement initiatives intended to further optimize the BAT. 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 have a material adverse effect on our business.

The April 2009 Complete Response letter and the outcome of the June 2, 2009 meeting with the FDA have caused us to make fundamental changes in our business strategy 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 incurred a one-time charge of $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 KL_4 surfactant technology, including our quality, manufacturing and research and development resources and continue to make investments in our proprietary KL_4 surfactant technology pipeline programs.

Following the June 2, 2009 meeting with the FDA, we have made fundamental changes in our business strategy. To secure capital and advance our KL4 surfactant pipeline programs, we are seeking to reduce our financial burden by entering into strategic alliances in all markets, including, the United States. We are now seeking alliances that potentially provide non-dilutive capital in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses, and that leverage the individual expertise and capabilities of the parties. In addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements, including potentially satisfying our loan with Novaquest, and continue our operations. As we continue to manage our cash resources and work towards securing potential strategic alliances, we are scaling back our investment in our research and development programs, which will likely cause us to experience additional delays. While we remain reasonably confident that we can achieve our goals, our timelines may be extended. Also, as we reassess our regulatory position and financial resources, 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.

Our revised business plan, if successful, will cause us to be dependent upon strategic partners to fund and support our research and development initiatives and for the marketing and sales of our drug and drug-device combination products, both in the United States and in international markets, which will subject us to risks and uncertainties.

Prior to receipt of the Complete Response letter, we planned to develop by ourselves our KL_4 surfactant products for neonatal and pediatric applications in the United States and, if our products are approved, we planned to build a fully-integrated pediatric franchise with our own specialty pulmonary commercial organization in the United States. We have now revised this strategy and are seeking strategic alliances in all markets, including the United States. If we successfully secure such strategic alliances, our ability to execute our current operating plan will be dependent on numerous factors, including, the performance of third-party strategic partners and collaborators with whom we may contract. 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 development strategies and in the alternatives for the commercialization of our products. If we are successful in entering into strategic alliance agreements, if we breach or terminate the agreements that make up these arrangements or if our strategic 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. If we fail to successfully develop these relationships or if our 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 our products.

In addition, as we no longer plan to build our own sales and marketing organization in the United States, we will be dependent upon strategic partners for the marketing and sales of our KL_4 surfactant products. 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.

In light of the change in our business strategy and our change in priority to Surfaxin LS and Aerosurf, we will require significant additional capital to continue our 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 any of our lead products, 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 we make prudent investments in preclinical studies and our drug product and device development programs, and focus our resources on being in a position to initiate key clinical programs only after we have secured appropriate strategic alliances and necessary capital. 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 strategic alliances or, in the alternative, future debt and equity financings, we may be forced to further limit many, if not all, of our programs, which could have a material adverse impact on our business plan.

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 strategic and collaborative ventures with potential partners and/or future debt and equity financings, 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, as of June 30, 2009, we have authorized capital available for issuance (and not otherwise reserved) of approximately 300,000 shares of common stock. 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. 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 significantly 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.

In addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities to meet our capital requirements, including potentially satisfying our loan with Novaquest, and continue our operations. Although we are hopeful that we can achieve one or more strategic alliances in our key target markets, there can be no assurance that any such strategic alliance or any alternative financing to will be achieved.

We are advised that the Nasdaq Stock Market LLC (Nasdaq) is reinstating the listing requirement that a company's stock must trade above a minimum price of $1.00 per share, which subjects us to the risk of delisting, which would impair the liquidity of our securities and cause our stock price to decline.

In response to the ongoing financial crisis and markets disruptions, Nasdaq temporarily suspended its listing requirement that a company's stock must trade at a minimum price of $1.00 per share. Nasdaq has advised us that it is reinstating this listing requirement effective August 3, 2009. Accordingly, if the closing price of our common stock closes below $1.00 for 30 consecutive business days after August 3, 2009, we will receive a deficiency notice from Nasdaq. Nasdaq will then allow a 180-day period during which we can regain compliance by meeting the $1.00 minimum bid price standard for at least 10 consecutive business days. If we fail to regain compliance prior to the expiration of the 180-day period, assuming we are in compliance with all other applicable standards for initial listing on the Nasdaq Capital Market, under current rules, we could then elect to transfer to the Nasdaq Capital Market, which would grant us an additional 180 days to regain compliance. If our stock price does not exceed the minimum bid price of $1.00 within the time frames set forth above, our securities will be subject to delisting. Since announcing the results of the June 2, 2009 meeting with the FDA on July 1, 2009, through August 6, 2009, our stock price has closed below $1.00 per share. If our common stock were no longer listed on The Nasdaq Global Market or the Nasdaq Capital Market, investors might only be able to trade in the over-the-counter market in the Pink Sheets® (a quotation medium operated by Pink OTC Markets Inc.) or on the OTC Bulletin Board® of the Financial Industry Regulatory Authority, Inc. (FINRA). This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

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

During the three and six months ended June 30, 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 and six months ended June 30, 2009.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

We anticipated that Surfaxin may have been approved in April 2009, which was the approximate time for printing and mailing our Proxy Statement if the 2009 Annual Meeting were scheduled at the same time in the year as the 2008 Annual Meeting. As the FDA's decision with respect to Surfaxin was one consideration defining the substance of proposals to be included in our Proxy Statement, we determined to delay scheduling the 2009 Annual Meeting to have the opportunity to respond to the FDA's decision. In addition, to meet our capital requirements including potentially satisfying our loan with Novaquest, in addition to multiple strategic alternatives, we continue to consider potential additional financings and other similar opportunities. We anticipate that such transactions, if achieved, may require stockholder approval.

Accordingly, we have determined to defer the scheduling our 2009 Annual Meeting until such time as discussions with certain interested parties concerning potential strategic alliances have advanced. In any event, we expect that the 2009 Annual Meeting of Stockholders will be scheduled to occur in the October / November timeframe. When the date of the 2009 Annual Meeting is finally determined, we will issue a notice that complies with the requirements of Rule 14a-d(f) and Rule 14a-8(e) under the Securities Exchange Act of 1934, as amended. It is expected that the 2009 proxy statement will set forth the timeline for stockholder proposals to be included in the 2010 proxy statement.

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: August 10, 2009

By: /s/ W. Thomas Amick
W. Thomas Amick
Chairman of the Board and Principal Executive Officer

Date: August 10, 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.

Exhibit No.	Description	Method of Filing
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.

Exhibit No.	Description	Method of Filing
4.6	Second Amended and Restated Promissory Note, dated as of October 25, 2006, issued to PharmaBio Development Inc. (“PharmaBio”)	Incorporated by reference to Exhibit 4.1 to Discovery’s Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.7	Warrant Agreement, dated as of October 25, 2006, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.2 to Discovery’s Current Report on Form 8-K, as filed with the SEC on October 26, 2006.
4.8	Warrant Agreement, dated November 22, 2006	Incorporated by reference to Exhibit 4.1 to Discovery’s Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
4.9	Warrant Agreement dated May 22, 2008 by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 4.1 to Discovery’s Current Report on Form 8-K as filed with the SEC on May 28, 2008.
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.
4.11	Form of Warrant Agreement dated May 13, 2009	Incorporated by reference to Exhibit 10.3 to Discovery’s Current Report on Form 8-K, as filed with the SEC on May 8, 2009.
31.1	Certification of Principal 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 Principal 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.

Exhibit 31.1

CERTIFICATIONS

I, W. Thomas Amick, 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: August 10, 2009

/s/ W. Thomas Amick

W. Thomas Amick
Chairman of the Board and Principal Executive Officer

Exhibit 31.2

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: August 10, 2009

/s/ John G. Cooper

John G. Cooper
Executive Vice President and Chief Financial Officer

Exhibit 32.1

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 June 30, 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: August 10, 2009

/s/ W. Thomas Amick
W. Thomas Amick
Chairman of the Board and Principal 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.