

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

**FORM 10-Q/A**  
Amendment No. 1

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

For the quarterly period ended March 31, 2010

or

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

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

Commission file number 000-26422

**DISCOVERY LABORATORIES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**94-3171943**

(I.R.S. Employer  
Identification Number)

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

**(215) 488-9300**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

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

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

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

As of November 12, 2010, 206,652,815 shares of the registrant's common stock, par value \$0.001 per share, were outstanding.

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## EXPLANATORY NOTE

We are filing this Amendment No. 1 to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010 (“Quarterly Report on Form 10-Q”), which was filed with the Securities and Exchange Commission on May 10, 2010, to: (i) amend Item 1 – “Financial Statements” to restate our financial statements for the quarter ended March 31, 2010 to reflect the reclassification of certain warrants from equity to liabilities, as discussed below, (ii) to make corresponding amendments to the following sections Item 2 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations” (“MD&A”): Results of Operations (first sentence, “Change in Fair Value of Common Stock Warrant Liability,”) and Liquidity and Capital Resources – Cash Flows – Cash Flows Used in Operating Activities, (iii) to amend Item 4 – “Controls and Procedures” to reflect a reassessment of our disclosure controls and procedures, and internal control over financial reporting, as of March 31, 2010 in light of the restatement of our financial statements for the quarter ended March 31, 2010, and (iv) to amend Part II – Item 1A – “Risk Factors” to add to the risk factors previously provided in our Quarterly Report on Form 10-Q additional risk factors related to the restatement of our financial statements.

Other than the foregoing, and the new certifications required by Rule 13a-14 under the Securities and Exchange Act of 1934 (“Exchange Act”), our Quarterly Report on Form 10-Q is not being amended or updated in any respect. This Amendment No. 1 continues to describe the conditions as of the date of the Quarterly Report on Form 10-Q, and, except as contained herein, we have not modified or updated the disclosures contained in the Quarterly Report on Form 10-Q. This Amendment No. 1 should be read in conjunction with our filings made with the SEC subsequent to the filing of the Quarterly Report on Form 10-Q, including any amendment to those filings.

As reported on our Current Report on Form 8-K filed on November 9, 2010, the Audit Committee of our Board of Directors concluded that the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2009, and the Quarterly Reports on Form 10-Q for the periods ended March 31, 2010 and June 30, 2010, should be restated to reclassify certain warrants that we issued in May 2009 and February 2010 as liabilities based on a reassessment of the applicable accounting guidance. See Note 2 to our consolidated financial statements.

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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 Amendment No. 1 contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 (“Securities Act”) and Section 21E of the Exchange Act. The forward-looking statements include all matters that are not historical facts. 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. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements in this report are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those set forth under “Risk Factors” and “Management’s Discussion and Analysis of Financial Conditions and Results of Operations” in our Annual Report on Form 10-K, as amended, and in our periodic reports on Forms 8-K and Form 10-Q, as amended, and elsewhere in this Amendment No. 1.

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)*

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
	<u>(Unaudited)</u>	<u>(As Restated)</u>
	<u>(As Restated)</u>	<u>(As Restated)</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 24,172	\$ 15,741
Prepaid expenses and other current assets	270	233
Total Current Assets	24,442	15,974
Property and equipment, net	4,444	4,668
Restricted cash	400	400
Other assets	223	361
Total Assets	<u>\$ 29,509</u>	<u>\$ 21,403</u>
<b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 1,147	\$ 1,294
Accrued expenses	3,531	3,446
Common stock warrant liability	7,662	3,191
Loan payable, including accrued interest	10,545	10,461
Equipment loans and capitalized leases, current portion	472	597
Total Current Liabilities	23,357	18,989
Equipment loans and capitalized leases, non-current portion	405	428
Other liabilities	673	690
Total Liabilities	24,435	20,107
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized; no shares issued or outstanding	-	-
Common stock, \$0.001 par value; 380,000 shares authorized; 154,325 and 126,689 shares issued, 154,012 and 126,376 shares outstanding	154	127
Additional paid-in capital	371,313	361,503
Accumulated deficit	(363,339)	(357,280)
Treasury stock (at cost); 313 shares	(3,054)	(3,054)
Total Stockholders' Equity	5,074	1,296
Total Liabilities & Stockholders' Equity	<u>\$ 29,509</u>	<u>\$ 21,403</u>

*See notes to consolidated financial statements*

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

(Unaudited)

*(in thousands, except per share data)*

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<u>(As Restated)</u>	
Revenue	\$ -	\$ -
Expenses:		
Research and development	4,133	5,607
General and administrative	2,932	3,096
Total expenses	<u>7,065</u>	<u>8,703</u>
Operating loss	(7,065)	(8,703)
Change in fair value of common stock liability	1,230	-
Other income / (expense):		
Interest and other income	19	5
Interest and other expense	(242)	(302)
Other income / (expense), net	<u>(223)</u>	<u>(297)</u>
Net loss	<u>\$ (6,058)</u>	<u>\$ (9,000)</u>
Net loss per common share –		
Basic and diluted	\$ (0.04)	\$ (0.09)
Weighted average number of common shares outstanding – basic and diluted	137,699	102,093

*See notes to consolidated financial statements*

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

(Unaudited)

*(in thousands)*

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(As Restated)</b>	
<b>Cash flows from operating activities:</b>		
Net loss	\$ (6,058)	\$ (9,000)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	482	516
Stock-based compensation and 401(k) match	455	976
Fair value adjustment of common stock warrants	(1,230)	
Gain on sale of equipment	(16)	–
<b>Changes in:</b>		
Prepaid expenses and other current assets	(37)	287
Accounts payable	(147)	(230)
Accrued expenses	85	(160)
Other assets	1	1
Other liabilities and accrued interest on loan payable	67	92
Net cash used in operating activities	<u>(6,398)</u>	<u>(7,518)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(57)	(53)
Restricted cash	–	200
Proceeds from sales or maturity of marketable securities	–	2,047
Net cash used in investing activities	<u>(57)</u>	<u>2,194</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of securities, net of expenses	15,082	2,531
Principal payments under equipment loan and capital lease obligations	(196)	(826)
Net cash provided by financing activities	<u>14,886</u>	<u>1,705</u>
Net increase / (decrease) in cash and cash equivalents	8,431	(3,619)
Cash and cash equivalents – beginning of period	<u>15,741</u>	<u>22,744</u>
Cash and cash equivalents – end of period	<u>\$ 24,172</u>	<u>\$ 19,125</u>
<b>Supplementary disclosure of cash flows information:</b>		
Interest paid	\$ 21	\$ 84
<b>Non-cash transactions:</b>		
Unrealized loss on marketable securities	–	(1)
Equipment acquired through capitalized lease	48	–

*See notes to consolidated financial statements*

## **Notes to Consolidated Financial Statements (unaudited)**

### **Restatement of Historical Financial Statements**

The accompanying Consolidated Balance Sheet as of March 31, 2010 and the Consolidated Statement of Operations and Cash Flows for the quarter ended March 31, 2010, have been restated in this report to reclassify certain warrants based on a reassessment of the applicable accounting guidance, as discussed in Note 2

### **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 therapies to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel KL<sub>4</sub> proprietary technology produces a synthetic, peptide-containing surfactant (KL<sub>4</sub> 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<sub>4</sub> surfactant to the 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 developing our lead products, Surfaxin<sup>®</sup> (lucinactant), Surfaxin LS<sup>™</sup> and Aerosurf<sup>®</sup>, to address the most significant respiratory conditions affecting pediatric populations. In April 2009, we received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) with respect to our New Drug Application (NDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, our first product based on our novel KL<sub>4</sub> surfactant technology. The letter focused primarily on certain aspects of our fetal rabbit biological activity test (BAT, a quality control and stability release test for Surfaxin and our other KL<sub>4</sub> pipeline products), specifically whether analysis of preclinical data from both the BAT and a well-established preterm lamb model of RDS demonstrates the degree of comparability that the FDA requires and whether the BAT can adequately distinguish change in Surfaxin biological activity over time. Based on meetings held in June and September 2009 and other interactions with the FDA, we have optimized the BAT and have recently completed the laboratory testing to re-validate the optimized BAT. We expect to complete our revalidation efforts in May 2010. See, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Overview – Business Strategy Update.”

Following completion of the BAT optimization and revalidation, to address the sole remaining issue for Surfaxin approval, we plan to initiate a comprehensive program that will consist of a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and a well-established preterm lamb model of RDS. We submitted the protocol for these studies to the FDA for its review and now expect a written response from the FDA in May 2010. Subject to confirmation that we have satisfactorily revalidated the BAT, we expect to initiate the side-by-side preclinical programs in the next few months. We believe that we remain on track to complete our comprehensive program and submit our Complete Response to the FDA in the first quarter of 2011, which could potentially lead to approval of Surfaxin for the prevention of RDS in premature infants in 2011. If approved, Surfaxin would be the first synthetic, peptide-containing surfactant for use in pediatric medicine.

Surfaxin LS, our lyophilized KL<sub>4</sub> surfactant, is a dry powder formulation that is resuspended as a liquid prior to use. Surfaxin LS is intended to improve ease of use for healthcare practitioners, eliminate the need for cold-chain storage, and potentially further improve clinical performance. Aerosurf is our proprietary KL<sub>4</sub> surfactant in aerosolized form, which we are developing using our capillary aerosolization technology, initially to treat premature infants at risk for RDS. Premature infants with RDS are treated with surfactants that are administered by means of invasive endotracheal intubation and mechanical ventilation, procedures that frequently result in serious respiratory conditions and complications. If approved, we believe that Aerosurf will make it possible to administer surfactant into the lung without subjecting patients to such invasive procedures. We believe that Aerosurf has the potential to enable a significant increase in the use of surfactant therapy in pediatric medicine.



In addition to our lead products, we plan over time to develop our KL<sub>4</sub> surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies, in patient populations ranging from premature infants to adults. Our plans include potentially taking these initiatives through a Phase 2 proof-of-concept phase and, if successful, thereafter determining whether to seek strategic alliances or collaboration arrangements or to utilize other financial alternatives to fund their further development. We have recently completed enrollment in a Phase 2 clinical trial of Surfaxin to potentially address Acute Respiratory Failure (ARF) and expect that top line results will be available in the second quarter 2010. Our KL<sub>4</sub> surfactant is also the subject of an investigator-initiated Phase 2a clinical trial assessing the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL<sub>4</sub> surfactant in patients with Cystic Fibrosis (CF). We are conducting research and preclinical development with our KL<sub>4</sub> surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have also initiated exploratory preclinical studies to assess the feasibility of using our KL<sub>4</sub> surfactant in combination with small and large molecule therapeutics to efficiently and effectively deliver therapies to the lung to treat a range of pulmonary conditions and disease.

An important priority is to secure strategic and financial resources to potentially maximize the inherent value of our KL<sub>4</sub> surfactant technology. We prefer to accomplish our objectives through strategic alliances, including potential business alliances, and commercial and development partnerships. With respect to our lead products, we are engaged in discussions with potential strategic and/or financial partners. To secure required capital, we are also considering other alternatives, including additional financings and other similar opportunities. Although we continue to consider a number of potential strategic and financial alternatives, there can be no assurance that we will enter into any strategic alliance or otherwise consummate any financing or other similar opportunities. Until such time as we secure the necessary capital, we plan to continue conserving our financial resources, predominantly by limiting investments in our pipeline programs.

### **Basis of Presentation**

The accompanying interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. 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, 2009 that we filed with the Securities and Exchange Commission (SEC) on March 10, 2010 (2009 Annual Report on Form 10-K).

### **Note 2 – Restatement of Financial Statements**

In this Amendment No. 1, we have restated our previously issued consolidated financial statements and related disclosures for the quarter ended March 31, 2010, to correct errors in the accounting for certain warrants. Specifically, we previously classified as equity instruments warrants that should have been classified as derivative liability instruments based on the terms of the warrants and the applicable accounting guidance.

We have historically accounted for warrants, which prior to May 2009 were issued in private transactions, as equity instruments. Certain warrants issued in registered transactions in May 2009 and February 2010 generally provide that, in the event the related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares, the holder may exercise the warrant on a cashless basis. However, notwithstanding the availability of cashless exercise, generally accepted accounting principles establishes that, in the absence of express agreement of the parties to the contrary, registered warrants may be subject to net cash settlement, as it is not within the absolute control of the issuer to provide freely-tradable shares in all circumstances. The applicable accounting principles expressly do not allow for an evaluation of the likelihood that an event would trigger cash settlement.

The accompanying quarterly financial statements have been restated to report the warrants issued in May 2009 and February 2010 as derivative liabilities measured at estimated fair value, calculated using the Black-Scholes option pricing model:

Issuance Date	Number of Warrants Issued	Exercise Price	Expiration of Warrants	Fair Value of Warrants at Issuance Date
May 13, 2009	7,000,000	\$1.15	May 13, 2014	\$3,360
February 23, 2010	13,750,000	\$0.85	February 23, 2015	\$5,701

(In thousands)

The following tables summarize the effect of the restatement on the specific items presented in our historical consolidated financial statements included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010:

<b>Consolidated Balance Sheet</b> <i>(in thousands)</i>	March 31, 2010 <i>(As previously reported)</i>	March 31, 2010 <i>(As restated)</i>
<b>Current Liabilities:</b>		
Common stock warrant liability	\$ --	\$ 7,662
<b>Total Current Liabilities</b>	<b>15,695</b>	<b>23,357</b>
<b>Total Liabilities</b>	<b>16,773</b>	<b>24,435</b>
<b>Stockholders' Equity:</b>		
Additional paid-in-capital	380,573	371,313
Accumulated deficit	(364,937)	(363,339)
<b>Total Stockholders' equity</b>	<b>12,736</b>	<b>5,074</b>
<b>Consolidated Statement of Operations</b> <i>(in thousands)</i>		
	Quarter Ended March 31, 2010 <i>(As previously reported)</i>	Quarter Ended March 31, 2010 <i>(As restated)</i>
Change in fair value of common stock warrant liability	\$ --	\$ 1,230
<b>Net Loss</b>	<b>(7,288)</b>	<b>(6,058)</b>
<b>Loss per share</b>	<b>\$ (0.05)</b>	<b>\$ (0.04)</b>
<b>Consolidated Statement of Cash Flows</b> <i>(in thousands)</i>		
	Quarter Ended March 31, 2010 <i>(As previously reported)</i>	Quarter Ended March 31, 2010 <i>(As restated)</i>
<b>Net Loss</b>	<b>\$ (7,288)</b>	<b>\$ (6,058)</b>
Fair value adjustment of common stock warrants	--	(1,230)

### Note 3 – Liquidity Risks and Management’s Plans

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

Following receipt from the FDA of a Complete Response Letter for Surfaxin in April 2009, we made fundamental changes in our business strategy. We now believe that it is in our best interest financially to seek to develop and commercialize our KL<sub>4</sub> technology through strategic alliances or other collaboration arrangements, including in the United States. However, there can be no assurance that any strategic alliance or other arrangement will be successfully concluded.

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. As a result of our cash position as of December 31, 2009, the audit opinion we received from our independent auditors for the year ended December 31, 2009 contains a notation related to our ability to continue as a going concern. 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 arrangements 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 that event, we may be forced to further limit development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, 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. Our financial statements 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.

Our future capital requirements will depend upon many factors, including our efforts to secure one or more strategic alliances to support our product development activities and commercialization plans, and the ultimate success of our product development and commercialization plans. Currently, we are focused on developing our lead KL<sub>4</sub> surfactant products 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 secure strategic alliances or obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in securing strategic alliances, raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of March 31, 2010, we had cash and cash equivalents of \$24.2 million, which includes net proceeds of \$15.1 million (\$16.5 million gross) from a public offering that we completed in February 2010. As of May 7, 2010, neither the May 2008 CEFF nor the December 2008 CEFF was available to us because the closing market price of our common stock (\$0.47) was below the minimum price required (\$1.15 and \$0.60, respectively) to utilize the facility. If and when the CEFFs become available, we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$69.5 million. See, Note 5 – Stockholders’ Equity, for details about our CEFFs.

As of March 31, 2010, our \$10.5 million loan with PharmaBio Development Inc (PharmaBio), the former strategic investment subsidiary of Quintiles Transnational Corp. (Quintiles), was classified as a current liability payable on April 30, 2010. On April 28, 2010, we completed a restructuring of the loan (\$10.6M at the time of restructuring) pursuant to a Payment Agreement and Loan Amendment dated April 27, 2010 (PharmaBio Agreement) that provided for (a) payment in cash of an aggregate of \$6.6 million, representing \$4.5 million in outstanding principal and \$2.1 million in accrued interest, (b) a maturity date extension for the remaining \$4 million principal amount under the loan, \$2 million of which now will be due and payable on July 30, 2010 and the remaining \$2 million of which will be due and payable on September 30, 2010, and (c) so long as we timely make each of the remaining principal payments on or before their respective due dates, no further interest will accrue on the outstanding principal amount. In addition, we agreed to maintain (i) at least \$10 million in cash and cash equivalents until payment of the first \$2 million installment is made on or before July 30, 2010, and (ii) at least \$8 million in cash and cash equivalents until the payment of the second \$2 million installment on or before September 30, 2010, after which the PharmaBio loan will be paid in full. Also under the PharmaBio Agreement, PharmaBio surrendered to us for cancellation warrants to purchase an aggregate of 2,393,612 shares of our common stock that we had issued previously to PharmaBio in connection with the PharmaBio loan and a previous offering of securities. See, Note 9 – Subsequent Events.

The PharmaBio Agreement also provides that we and PharmaBio will negotiate in good faith to potentially enter into a strategic arrangement under which PharmaBio would provide funding for a research collaboration between Quintiles and us relating to the possible research and development, and commercialization of two of our drug product candidates, Surfaxin LS and Aerosurf, for the prevention and treatment of RDS in premature infants. However, neither party is obligated to enter into any such arrangement except to the extent that the parties, in their individual and sole discretion, enter into definitive documents with respect thereto. Accordingly, there can be no assurances that any such arrangement will be completed. See, Note 9 – Subsequent Events.

Also on April 27, 2010, we entered into a Securities Purchase Agreement pursuant to which PharmaBio agreed to purchase 4,052,312 shares of our common stock and warrants to purchase an aggregate of 2,026,156 shares of common stock, resulting in gross proceeds to us, on April 29, 2010, of \$2.2 million (\$2.1 million net). The shares of common stock and warrants were sold as units, with each unit consisting of (a) one share of common stock, and (b) one-half of a warrant to purchase a share of common stock, at an offering price of \$0.5429 per unit. The warrants generally will be exercisable beginning 181 days after the date of issuance for a period of five years from the original date of issuance at an exercise price of \$0.7058 per share. See, Note 5 – Stockholders' Equity, and Note 9 – Subsequent Events.

#### **Note 4 – Accounting Policies and Recent Accounting Pronouncements**

##### Accounting policies

There have been no changes to our critical accounting policies since December 31, 2009. For more information on critical accounting policies, see, Note 4 – “Summary of Significant Accounting Policies and Recent Accounting Pronouncements” to the consolidated financial statements included in our 2009 Annual Report on Form 10-K, as amended. Readers are encouraged to review those disclosures in conjunction with the review of our Quarterly Report on Form 10-Q and this Amendment No. 1.

##### 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 March 31, 2010 and 2009, 44.0 million and 24.8 million shares of common stock, respectively, were potentially issuable upon the exercise of certain stock options and warrants. Due to our net loss, these potentially issuable shares were not included in the calculation of diluted net loss per share as the effect would be anti-dilutive, therefore basic and dilutive net loss per share are the same.

### Comprehensive loss

Comprehensive loss consists of net loss plus the changes in unrealized gains and losses on available-for-sale securities. Comprehensive loss for the three months ended March 31, 2010 and 2009 are as follows:

(in thousands)	For the three months ended	
	March 31,	
	2010	2009
	(As restated)	
Net loss	\$ (6,058)	\$ (9,000)
Change in unrealized gains/(losses) on marketable securities	—	(1)
Comprehensive loss	<u>\$ (6,058)</u>	<u>\$ (9,001)</u>

### Recent accounting pronouncements

In March 2010, ASU 2010-17, *Revenue Recognition—Milestone Method* (Topic 605): *Milestone Method of Revenue Recognition—a consensus of the FASB Emerging Issues Task Force* (“ASU 2010-17”) was issued and will amend the accounting for revenue arrangements under which a vendor satisfies its performance obligations to a customer over a period of time, when the deliverable or unit of accounting is not within the scope of other authoritative literature, and when the arrangement consideration is contingent upon the achievement of a milestone. The amendment defines a milestone and clarifies whether an entity may recognize consideration earned from the achievement of a milestone in the period in which the milestone is achieved. This amendment is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. The amendment may be applied retrospectively to all arrangements or prospectively for milestones achieved after the effective date. We do not believe the adoption of this ASU will have a material impact on our financial statements.

### **Note 5 – Stockholders’ Equity**

#### Registered Public Offerings

In February 2010, we completed a public offering of 27.5 million shares of our common stock and warrants to purchase 13.8 million shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock, at a public offering price of \$0.60 per unit, resulting in gross proceeds to us of \$16.5 million (\$15.1 million net). This offering was made pursuant to a prospectus supplement dated April 28, 2010 and an accompanying prospectus dated June 18, 2008 pursuant to our existing shelf registration statement on Form S-3 (File No. 333-151654), which was filed with the SEC on June 13, 2008 and declared effective by the SEC on June 18, 2008 (2008 Shelf Registration Statement). The warrants expire in February 2015 and are exercisable, subject to an aggregate beneficial ownership limitation, at a price per share of \$0.85. The exercise price and number of shares of common stock issuable on exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction. The exercise price and the amount and/or type of property to be issued upon exercise of the warrants will also be subject to adjustment if the Company engages in a “Fundamental Transaction” (as defined in the form of warrant). The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not available for the resale of the warrant shares, the holder may exercise on a cashless basis.

In May 2009, we completed a registered direct public offering of 14.0 million shares of our common stock and warrants to purchase seven million shares of common stock, sold as units to select institutional investors, with each unit consisting of one share and a warrant to purchase 0.5 of a share of common stock, at a price of \$0.81 per unit, resulting in gross proceeds to us of \$11.3 million (\$10.5 million net). This offering was made pursuant to a prospectus supplement dated May 8, 2009 to the prospectus dated June 18, 2008 included in our 2008 Shelf Registration Statement. The warrants expire in May 2014 and are exercisable at a price per share of \$1.15. The exercise price and number of shares of common stock issuable on exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction. The exercise price and the amount and/or type of property to be issued upon exercise of the warrants will also be subject to adjustment if the Company engages in a "Fundamental Transaction" (as defined in the form of warrant). The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not available for the resale of the warrant shares, the holder may exercise on a cashless basis.

#### Common Stock Offering with PharmaBio Development Inc.

On April 27, 2010, we entered into a Securities Purchase Agreement with PharmaBio, as the sole purchaser, related to an offering of 4,052,312 shares of common stock and warrants to purchase an aggregate of 2,026,156 shares of common stock, sold as units, with each unit consisting of one share of common stock and one half of a warrant to purchase a share of common stock, at an offering price of \$0.5429 per unit, representing the greater of (a) the volume-weighted average sale price ("VWAP") per share of the common stock on The Nasdaq Global Market for the 20 trading days ending on April 27, 2010 and (b) the last reported closing price of \$0.5205 per share of the common stock on The Nasdaq Global Market on such date. The offering resulted in gross proceeds to us of \$2.2 million (\$2.1 million net). This offering was made pursuant to a prospectus supplement dated April 28, 2010 to the prospectus dated June 18, 2008 included in our 2008 Shelf Registration Statement. The warrants expire in April 2015 and generally will be exercisable beginning 181 days after the date of issuance, subject to an aggregate beneficial ownership limitation of 9.9%, at a price per share of \$0.7058, which represents a 30% premium to the VWAP for the 20 trading days ending on April 27, 2010. The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not available for the resale of the warrant shares, the holder may exercise on a cashless basis. *See also*, Note 9 – Subsequent Events.

#### Committed Equity Financing Facilities(CEFFs)

As of March 31, 2010, we had two CEFFs with Kingsbridge Capital Limited (Kingsbridge), under which Kingsbridge is committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFFs, dated December 12, 2008 (December 2008 CEFF) and May 22, 2008 (May 2008 CEFF), allow us at our discretion 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. We are not obligated to utilize any of the funds available under the CEFFs. Our ability to access funds available under the CEFFs is subject to certain conditions, including stock price and volume limitations.

Under the December 2008 CEFF, as of March 31, 2010, we had 7.1 million shares potentially available for issuance (up to a maximum of \$17.7 million), provided that the VWAP of our common stock on each trading day must be at least equal to the greater of (i) \$.60 or (ii) 90% of the closing price of our common stock on the trading day immediately preceding the draw down period (Minimum VWAP). Under the May 2008 CEFF, as of March 31, 2010, we had approximately 12.8 million shares potentially available for issuance (up to a maximum of \$51.7 million), provided that the VWAP on each trading day must be at least equal to 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*, "Item 7 –Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs)" included in our 2009 Annual Report on Form 10-K. As of May 7, 2010, neither CEFF is currently available because the market price of our common stock is less than the minimum price required to utilize either CEFF.

To date, we have not utilized our CEFFs in 2010. During 2009, we raised an aggregate of \$10.7 million from 10 draw-downs under our CEFFs. If and when the closing market price of our common stock is at least equal to the minimum price required under our CEFFs, we anticipate using them to support our working capital needs and maintain cash availability in 2010.

## Note 6 – Fair Value of Financial Instruments

We adopted the provisions of ASC Topic 820, *Fair Value Measurements and Disclosures*, which defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements.

Under ASC Topic 820, 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 must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is 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 1 is generally considered the most reliable measurement of fair value under ASC 820.
- 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 and liabilities measured at fair value on a recurring basis are categorized in the table below as of March 31, 2010:

(in thousands)	<u>Fair Value</u>	<u>Fair value measurement using</u>		
	<u>March 31,</u> <u>2010</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>Assets:</b>				
Money markets (1)	\$ 21,890	\$ 21,890	\$ –	\$ –
Certificate of deposit	400	400	–	–
Total Assets	<u>\$ 22,290</u>	<u>\$ 22,290</u>	<u>\$ –</u>	<u>\$ –</u>
<b>Liabilities</b>				
Common stock warrant liability	<u>\$ 7,662</u>	<u>\$ –</u>	<u>\$ –</u>	<u>\$ 7,662</u>

(1) Dreyfus Treasury & Agency Cash Management Fund.

The following table summarizes the activity of Level 3 inputs measured on a recurring basis for the quarter ended March 31, 2010:

**Fair Value Measurements of Common Stock  
Warrants Using Significant Unobservable  
Inputs  
(Level 3)**

(in thousands)

Balance at December 31, 2009	\$	3,191
Issuance of common stock warrants		5,701
Change in fair value of common stock warrant liability		(1,230)
Balance at March 31, 2010	\$	7,662

**Note 7 – Stock Options and Stock-Based Employee Compensation**

We recognize all share-based payments to employees and non-employee directors in our financial statements based on their grant date fair values, calculated using the Black-Scholes option pricing model. Compensation expense related to share-based awards is recognized ratably over the requisite service period, typically three years for employees.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses weighted average assumptions noted in the following table.

	<u>March 31, 2010</u>	<u>March 31, 2009</u>
Expected volatility	99%	81%
Expected term	4.7 years	4.6 years
Risk-free interest rate	1.7%	2.1%
Expected dividends	–	–

The total employee stock-based compensation for the three months ended March 31, 2010 and 2009 was as follows:

<i>(in thousands)</i>	Three Months Ended March 31,	
	2010	2009
Research & Development	\$ 166	\$ 209
General & Administrative	232	670
Total	<u>\$ 398</u>	<u>\$ 879</u>

As of March 31, 2010, there was \$1.8 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 (2007 Plan). That cost is expected to be recognized over a weighted-average vesting period of 1.1 years.

**Note 8 – Contractual Obligations and Commitments**

*Former CEO Commitment*

In connection with the resignation in August 2009 of Robert J. Capetola, Ph.D., our former President, Chief Executive Officer and member of our Board of Directors, we entered into a separation agreement and general release (the “Separation Agreement”) dated August 13, 2009, that provided, among other things, for periodic severance payments through the earlier of (i) May 3, 2010 (Severance Period) or (ii) the date, if ever, of a Corporate Transaction (defined below). Under the Separation Agreement, if a Corporate Transaction were to occur during the Severance Period, Dr. Capetola would become entitled to receive an additional severance payment of up to \$1,580,000 or, if any such Corporate Transaction were to constitute a Change of Control, a payment of up to \$1,777,500; provided, however, that in each case, any such payment is reduced by the sum of the aggregate cash severance amounts already paid under the Separation Agreement.



A “Corporate Transaction” was defined in the Separation Agreement to include one or more public or private financings that were completed during the Severance Period and resulted in cash proceeds (net of transaction costs) to us of at least \$20 million received during the Severance Period or within 90 calendar days thereafter. From August 13, 2009 through February 23, 2010, we raised approximately \$21.0 million of aggregate net proceeds, consisting of approximately \$5.9 million from financing transactions under our CEFFs throughout the period and \$15.1 million from a public offering that was completed on February 23, 2010. As these transactions satisfied the criteria for a Corporate Transaction under the Separation Agreement, on March 3, 2010, we paid to Dr. Capetola an additional \$1.06 million (less withholding), representing \$1.58 million reduced by the sum of the cash severance amounts previously paid under the Separation Agreement, which totaled approximately \$0.52 million. At this time, our obligation to make periodic payments under the Separation Agreement has been satisfied and no further payments are due to Dr. Capetola.

The full text of the Separation Agreement is attached to our Current Report on Form 8-K that we filed with the SEC on August 19, 2009. For a summary of the Separation Agreement, see, “Item 11– Executive Compensation –Resignation of our President and Chief Executive Officer,” in our Amendment No. 1 to our 2009 Annual Report on Form 10-K that we filed with the SEC on April 30, 2010 (2009 Form 10-K/A).

#### **Note 9– Subsequent Events**

We evaluated all events or transactions that occurred after March 31, 2010 up through the date we issued these financial statements. During this period we did not have any material recognized subsequent events, however, there was one nonrecognized subsequent event described below:

##### *Loan Restructuring – PharmaBio Development Inc.*

As of March 31, 2010, our \$10.5 million loan with PharmaBio was classified as a current liability, payable on April 30, 2010. On April 27, 2010, we entered into the PharmaBio Agreement and on April 28, 2010, completed a restructuring of the loan (\$10.6M at the time of restructuring). The PharmaBio Agreement provided for (a) payment in cash of an aggregate of \$6.6 million, representing \$4.5 million in outstanding principal and \$2.1 million in accrued interest, (b) a maturity date extension for the remaining \$4 million principal amount under the loan, \$2 million of which now will be due and payable on July 30, 2010 and the remaining \$2 million of which will be due and payable on September 30, 2010, and (c) so long as we timely make each of the remaining principal payments on or before their respective due dates, no further interest will accrue on the outstanding principal amount. In addition, we agreed to maintain (i) at least \$10 million in cash and cash equivalents until payment of the first \$2 million installment is made on or before July 30, 2010, and (ii) at least \$8 million in cash and cash equivalents until the payment of the second \$2 million installment on or before September 30, 2010, after which the PharmaBio loan will be paid in full. Also under the PharmaBio Agreement, PharmaBio surrendered to us for cancellation the following warrants to purchase an aggregate of 2,393,612 shares of our common stock that we had issued previously to PharmaBio in connection with the PharmaBio loan and a previous offering of securities: a warrant to purchase 850,000 shares of common stock at \$7.19 per share expiring on November 3, 2014, a warrant to purchase 1,500,000 shares of common stock at \$3.58 per share expiring on October 26, 2013 and a warrant to purchase 43,612 shares of the Company’s common stock at \$6.875 per share expiring on September 19, 2010.

The PharmaBio Agreement also provided that we and PharmaBio would negotiate in good faith to potentially enter into a strategic arrangement under which PharmaBio would provide funding for a research collaboration between Quintiles and us relating to the possible research and development, and commercialization of two of our drug product candidates, Surfaxin LS and Aerosurf, for the prevention and treatment of RDS in premature infants. However, neither party is obligated to enter into any such arrangement except to the extent that the parties, in their individual and sole discretion, enter into definitive documents with respect thereto. Accordingly, there can be no assurances that any such arrangement or collaboration will be completed.

Also, on April 27, 2010, we entered into a Securities Purchase Agreement pursuant to which PharmaBio agreed to purchase 4,052,312 shares of our common stock and warrants to purchase an aggregate of 2,026,156 shares of our common stock, resulting in gross proceeds to us, on April 29, 2010, of \$2.2 million (\$2.1 million net). The shares of common stock and warrants were sold as units, with each unit consisting of (a) one share of common stock, and (b) one-half of a warrant to purchase a share of common stock, at an offering price of \$0.5429 per unit. The offering price per unit was calculated based on the greater of (a) the VWAP per share of the common stock on The Nasdaq Global Market for the 20 trading days ending on April 27, 2010 and (b) the last reported closing price of \$0.5205 per share of the common stock on The Nasdaq Global Market on such date. The warrants generally will be exercisable beginning 181 days after the date of issuance for a period of five years from the original date of issuance at an exercise price of \$0.7058 per share, which represents a 30% premium to the VWAP. The exercise price and number of shares of our common stock issuable on exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction. The exercise price and the amount and/or type of property to be issued upon exercise of the warrants will also be subject to adjustment if we engage in a “Fundamental Transaction” (as defined in the Warrant). This offering was made pursuant to our 2008 Shelf Registration Statement. The offering closed on April 30, 2010.

See Also, Note 3 – Liquidity Risks and Management’s Plans, and Note 5 – Stockholders’ Equity – Common Stock Offering with PharmaBio Development Inc. The full text of the PharmaBio Agreement, the Warrant and the Securities Purchase Agreement is attached as exhibits to our Current Report on Form 8-K that we filed with the SEC on April 28, 2010.

## **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” (“MD&A”) is provided as a supplement to the accompanying interim unaudited consolidated financial statements and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. This item should be read in connection with our accompanying interim unaudited consolidated financial statements (including the notes thereto) appearing elsewhere herein.

### **RESTATEMENT OF PREVIOUSLY-ISSUED CONSOLIDATED FINANCIAL STATEMENTS**

In this Amendment No. 1, we have restated our previously-issued consolidated financial statements and related disclosures for the quarter ended March 31, 2010 to reclassify warrants that we issued in February 2010, based on a reassessment of the applicable accounting guidance. We are also making corresponding amendments to the following sections of MD&A: Results of Operations (first sentence, “Change in Fair Value of Common Stock Warrant Liability,”) and Liquidity and Capital Resources – Cash Flows – Cash Flows Used in Operating Activities.

### **OVERVIEW**

Discovery Laboratories, Inc. (referred to as “we,” “us,” or the “Company”) is a biotechnology company developing surfactant therapies to treat respiratory disorders and diseases for which there frequently are few or no approved therapies. Our novel KL<sub>4</sub> proprietary technology produces a synthetic, peptide-containing surfactant (KL<sub>4</sub> 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<sub>4</sub> surfactant to the 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 developing our lead products, Surfaxin®(lucinactant), Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting pediatric populations. Our research and development efforts are currently focused on the management of RDS in premature infants. We have filed a New Drug Application (NDA) for our first product based on our novel KL<sub>4</sub> surfactant technology, Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in April 2009. We believe that the RDS market represents a significant opportunity from both a medical and a business perspective. We further believe that Surfaxin, Surfaxin LS and Aerosurf, have the potential to greatly improve the management of RDS and, collectively, represent the opportunity, over time, to significantly expand the current RDS worldwide annual market.

In addition to our lead products, we plan over time to develop our KL<sub>4</sub> surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies, in patient populations ranging from premature infants to adults. We have recently completed enrollment in a Phase 2 clinical trial of Surfaxin to potentially address Acute Respiratory Failure (ARF) and expect that top line results will be available in the second quarter 2010. Our KL<sub>4</sub> surfactant is also the subject of an investigator-initiated Phase 2a clinical trial assessing the safety, tolerability and short-term effectiveness (via improvement in mucociliary clearance) of aerosolized KL<sub>4</sub> surfactant in patients with Cystic Fibrosis (CF). We are conducting research and preclinical development with our KL<sub>4</sub> surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have also initiated exploratory preclinical studies to assess the feasibility of using our KL<sub>4</sub> surfactant in combination with small and large molecule therapeutics to efficiently and effectively deliver therapies to the lung to treat a range of pulmonary conditions and disease.

An important priority is to secure strategic and financial resources to potentially maximize the inherent value of our KL<sub>4</sub> surfactant technology. We prefer to accomplish our objectives through strategic alliances, including potential business alliances, commercial and development partnerships. With respect to our lead products, we are engaged in discussions with potential strategic and/or financial partners. In addition, our plans include potentially taking our early stage exploratory programs through a Phase 2 proof-of-concept phase and, if successful, thereafter determining whether to seek strategic alliances or collaboration arrangements or to utilize other financial alternatives to fund their further development. To secure required capital, we are also considering other alternatives, including additional financings and other similar opportunities. Although we continue to consider a number of potential strategic and financial alternatives, there can be no assurance that we will enter into any strategic alliance or otherwise consummate any financing or other similar opportunities. Until such time as we secure the necessary capital, we plan to continue conserving our financial resources, predominantly by limiting investments in our pipeline programs.

We have focused our current resources on our lead products, primarily to address the requirements to gain the potential approval of Surfaxin in the United States. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL<sub>4</sub> surfactant technology and support our operations, we will continue to conserve our resources, predominantly by curtailing and pacing investments in our pipeline programs.

### **Business Strategy Update**

The reader is referred to, and encouraged to read in its entirety “Item 1 – Business” included in our 2009 Annual Report on Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and our current and planned KL<sub>4</sub> pipeline programs.

The following are updates to our Business Strategy:

• Surfaxin for the Prevention of RDS in Premature infants

In response to written guidance received in February 2010 from the FDA, we are performing a comprehensive preclinical program to potentially address the sole remaining issue that was identified in the April 2009 Complete Response Letter. The letter focused primarily on certain aspects of our fetal rabbit biological activity test (BAT, a quality control and stability release test for Surfaxin and our other KL<sub>4</sub> pipeline products), specifically whether analysis of preclinical data from both the BAT and a well-established preterm lamb model of RDS demonstrates the degree of comparability that the FDA requires and whether the BAT can adequately distinguish change in Surfaxin biological activity over time. A key component of the comprehensive preclinical program is to first satisfactorily optimize and re-validate the BAT. To optimize the BAT, we executed a protocol that was previously submitted to the FDA for review and comment. We expect to complete our revalidation efforts in May 2010. Additionally, we have been interacting with the FDA regarding other important aspects of the comprehensive preclinical program, including our proposed study design and success criteria. We plan to initiate a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and a well-established preterm lamb model of RDS. We submitted the protocol for these studies to the FDA for its review and expect a written response from the FDA in the near future. Subject to confirmation that we have satisfactorily revalidated the BAT, we expect to initiate the side-by-side preclinical studies in the next few months. We believe that we remain on track to complete our comprehensive program and submit our Complete Response to the FDA in the first quarter of 2011, which could potentially lead to approval of Surfaxin for the prevention of RDS in premature infants in the United States in 2011.

• Surfaxin LS and Aerosurf Development Programs

We are currently conducting important preclinical activities for both Surfaxin LS and Aerosurf to support regulatory requirements for our planned clinical programs. We are preparing to further engage the FDA and interact with international regulatory agencies with respect to our planned Phase 3 clinical program for Surfaxin LS and our Phase 2 clinical program for Aerosurf. We are also taking steps to focus our capillary aerosolization device development activities on the capillary aerosolization device that we expect will support our Aerosurf clinical development programs. We intend to initiate these clinical programs upon determining a final regulatory strategy and after securing appropriate strategic alliances and necessary capital.

• Phase 2 Clinical Trials to Address Acute Respiratory Failure and Cystic Fibrosis

We have recently completed enrollment in a Phase 2 clinical trial to determine whether Surfaxin improves lung function and reduces the duration and related risk-exposure of mechanical ventilation in children up to two years of age diagnosed with Acute Respiratory Failure (ARF). ARF is a severe respiratory disorder associated with lung injury, often involving surfactant dysfunction. ARF occurs after patients have been exposed to serious respiratory infections, such as influenza (including the type A serotype referred to as H1N1) or respiratory syncytial virus (RSV). Top-line results of this trial are now expected to be available in June 2010.

Our aerosolized KL<sub>4</sub> surfactant is being evaluated in an investigator-initiated Phase 2a clinical trial in Cystic Fibrosis (CF) patients. The trial is being conducted at a leading research center, The University of North Carolina, and is further supported 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<sub>4</sub> surfactant in CF patients. Top line results for this trial are now expected in the third quarter of 2010.

As of March 31, 2010, we had cash and cash equivalents of \$24.2 million, which includes net proceeds of \$15.1 million (\$16.5 million gross) from a public offering that we completed in February 2010. Currently, under our two CEFFs, we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$69.5 million. However, as of May 7, 2010, neither the May 2008 CEFF nor the December 2008 CEFF was available because the market price of our common stock price was below the minimum price required (\$1.15 and \$0.60, respectively) to utilize the CEFFs. See, Note 5 – Stockholders' Equity, for details about our CEFFs.

As of March 31, 2010, our \$10.5 million loan with PharmaBio Development Inc., the former strategic investment subsidiary of Quintiles Transnational Corp (Quintiles), was classified as a current liability, payable on April 30, 2010. On April 28, 2010, we completed a restructuring of the loan (\$10.6M at the time of restructuring) under which we satisfied a portion of the loan and, as a result, the principal amount is now reduced to \$4 million, \$2 million of which will be due and payable on July 30, 2010 and the remaining \$2 million of which will be due and payable on September 30, 2010. For details of the terms of the restructuring, see, “– Liquidity and Capital Resources – Debt – Loan with PharmaBio Development, Inc.” We and PharmaBio also agreed to negotiate in good faith to potentially enter into a strategic arrangement under which PharmaBio would provide funding for a research collaboration between Quintiles and us relating to the research and development, and commercialization of Surfaxin LS and Aerosurf for the prevention and treatment of RDS in premature infants, although there can be no assurances that any such arrangement or collaboration will be accomplished. Also on April 30, 2010, we completed an offering of common stock and warrants to PharmaBio, resulting in gross proceeds to us of \$2.2 million (\$2.1 million net). See, “– Liquidity and Capital Resources – Common Stock Offerings – Financings under the 2008 Shelf Registration Statement.”

Our future capital requirements depend upon many factors, including the success of our efforts to secure one or more strategic alliances or other collaboration arrangements to support our product development activities and, if approved, commercialization plans. There can be no assurance, however, that we will be able to secure strategic partners or collaborators to support and advise our activities, 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. 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 securing strategic alliances, raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

### CRITICAL ACCOUNTING POLICIES

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. There have been no changes to our critical accounting policies since December 31, 2009. For more information on critical accounting policies, see our 2009 Annual Report on Form 10-K. Readers are encouraged to review these disclosures in conjunction with their review of this Form 10-Q.

### RESULTS OF OPERATIONS

The net loss for the three months ended March 31, 2010 and 2009 was \$6.1 million (or \$0.04 per share) and \$9.0 million (or \$0.09 per share), respectively.

#### Research and Development Expenses

Research and development expenses for the three months ended March 31, 2010 and 2009 were \$4.1 million and \$5.6 million, respectively. These costs are charged to operations as incurred and are tracked by category, as follows:

(in thousands)

Research and Development Expenses:	Three Months Ended March 31,	
	2010	2009
Manufacturing development	\$ 2,437	\$ 3,126
Development operations	1,241	1,752
Direct preclinical and clinical programs	455	729
<b>Total Research &amp; Development Expenses</b> <sup>(1)</sup>	<u>\$ 4,133</u>	<u>\$ 5,607</u>

<sup>(1)</sup> Included in research and development expenses are charges associated with stock-based employee compensation in accordance with the provisions of ASC Topic 718. For the three months ended March 31, 2010 and 2009, these charges were \$0.2 million and \$0.2 million, respectively.

### Manufacturing Development

Manufacturing development includes the cost of our manufacturing operations, quality assurance and analytical chemistry capabilities to assure adequate production of clinical and potential commercial drug supply for our KL<sub>4</sub> 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.

The decrease of \$0.7 million in manufacturing development expenses for the three months ended March 31, 2010, as compared to the same period in 2009, is primarily due to our efforts to conserve financial resources following receipt of the April 2009 Complete Response Letter and purchases in the first quarter of 2009 of active ingredients for the production of Surfaxin.

For the three months ended March 31, 2010 and 2009, manufacturing development expenses included charges associated with stock-based compensation of \$0.1 million and \$0.1 million, respectively.

### Development Operations

Development operations includes: (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our KL<sub>4</sub> surfactant development programs; (ii) medical affairs activities to provide scientific and medical education support in connection with our KL<sub>4</sub> surfactant technology pipeline programs; (iii) 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 planned Phase 2 clinical trials and; (iv) pharmaceutical development activities, including development of a lyophilized (dry powder) formulation of our KL<sub>4</sub> surfactant. These costs include personnel, expert consultants, outside services to support regulatory, data management and device development activities, symposiums at key neonatal medical meetings, facilities-related costs, and other costs for the management of clinical trials.

The decrease of \$0.5 million in development operations expenses for the three months ended March 31, 2010, as compared to the same period in 2009, is primarily due to our efforts to conserve financial resources following receipt of the April 2009 Complete Response Letter, including a reduction of our workforce and a restructuring of certain functions in research and development, primarily medical affairs.

For the three months ended March 31, 2010 and 2009, development operations expenses included charges associated with stock-based compensation of \$0.1 million and \$0.1 million, respectively.

### Direct Preclinical and Clinical Programs

Direct pre-clinical and clinical programs include: (i) pre-clinical activities, including toxicology studies and other pre-clinical studies to obtain data to support potential Investigational New Drug (IND) and NDA filings for our product candidates; (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; and (iii) activities related to addressing the items identified in the April 2009 Complete Response Letter.

Direct pre-clinical and clinical programs expenses for the three months ended March 31, 2010 included: (i) costs associated with activities to address issues identified in the April 2009 Complete Response Letter, including optimization and re-validation of the optimized BAT; (ii) activities associated with the ongoing Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering with ARF; and (iii) pre-clinical and preparatory activities for anticipated Phase 2 clinical trials for Surfaxin LS and Aerosurf for RDS in premature infants.

The decrease of \$0.3 million in direct preclinical and clinical program expenses for the three months ended March 31, 2010, as compared to the same period in 2009, is primarily due to costs in the first quarter of 2009 associated with preclinical activities and product characterization testing of our lyophilized form of Surfaxin, and our efforts to conserve financial resources following receipt of the April 2009 Complete Response Letter.

In an effort to conserve our financial resources, we plan to continue limiting investments in preclinical and clinical programs until we have secured appropriate strategic alliances and necessary capital. Where appropriate, we plan to meet with U.S. and European regulatory authorities to discuss the requirements for our regulatory packages, including potential trial design requirements, to prepare for our 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 months ended March 31, 2010 and 2009 were \$2.9 million and \$3.1 million, respectively. Included in general and administrative expenses for the three months ended March 31, 2010 was a one-time charge of \$1.0 million associated with certain contractual cash severance obligations to our former President and Chief Executive Officer. Additionally, for the three months ended March 31, 2010 and 2009, general and administrative expenses included charges associated with stock-based compensation of \$0.2 million and \$0.7 million, respectively.

Excluding the one-time charge related to our severance obligation and charges associated with stock based compensation, general and administrative expenses decreased \$0.7 million for the three months ended March 31, 2010, as compared to the same period in 2009. The decrease was primarily due to investments in pre-launch commercial capabilities in the first quarter of 2009 in anticipation of the potential approval and commercial launch of Surfaxin. Following receipt of the April 2009 Complete Response Letter for Surfaxin, to conserve our cash resources, we curtailed investment in commercial capabilities, 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 also made a fundamental change in our business strategy. To conserve financial resources, we no longer plan to establish our own specialty pulmonary commercial organization and we are instead seeking to develop and commercialize our KL<sub>4</sub> technology through strategic alliances or other collaboration arrangements, including in the United States. Although we are engaged in discussions with potential strategic and financial partners, there can be no assurance that any strategic alliance will be successfully concluded. Until such time as we secure an alliance or access to other capital, we continue to conserve our financial resources by predominantly limiting investments in our pipeline programs.

### Change in Fair Value of Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815 - "Derivatives and Hedging – Contracts in Entity's Own Equity" (ASC 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Derivative warrant liabilities are valued using the Black-Scholes pricing model at the date of initial issuance and each subsequent balance sheet date. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability."

The change in the fair value of common stock warrant liability for the three months ended March 31, 2010 resulted in income of \$1.2 million due primarily to a decrease in the Company's common stock share price during the period.

### Other Income and (Expense)

Other income and (expense) for the three months ended March 31, 2010 and 2009 were \$(0.2) million and \$(0.3) million, respectively.

<i>(Dollars in thousands)</i>	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Interest income	\$ 3	\$ 5
Interest expense	(242)	(302)
Realized gain on sale of equipment	16	–
Other income / (expense), net	<u>\$ (223)</u>	<u>\$ (297)</u>

Interest income consists of interest earned on our cash and marketable securities. To ensure preservation of capital, we invest most of our cash and marketable securities in a treasury-based money market fund.

Interest expense consists of interest accrued on the outstanding balance of our loan with PharmaBio and under our equipment financing facilities. In addition, interest expense includes expenses associated with the amortization of deferred financing costs for the warrant that we issued to PharmaBio in October 2006 as consideration for a restructuring of our loan in 2006. The decrease in interest expense for the three months ended March 31, 2010 as compared to the same periods for 2009 is due to a reduction in the outstanding principal balances on our equipment loans.

## LIQUIDITY AND CAPITAL RESOURCES

### Overview

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

Following receipt from the FDA of a Complete Response Letter for Surfaxin in April 2009, we made fundamental changes in our business strategy. We now believe that it is in our best interest financially to seek to develop and commercialize our KL<sub>4</sub> technology through strategic alliances or other collaboration arrangements, including in the United States. However, there can be no assurance that any strategic alliance or other arrangement will be successfully concluded.

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. As a result of our cash position as of December 31, 2009, the audit opinion we received from our independent auditors for the year ended December 31, 2009 contains a notation related to our ability to continue as a going concern. 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 arrangements 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 that event, we may be forced to further limit development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, and/or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our financial statements 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.

Our future capital requirements will depend upon many factors, including our efforts to secure one or more strategic alliances to support our product development activities and commercialization plans, and the ultimate success of our product development and commercialization plans. Currently, we are focused on developing our lead KL<sub>4</sub> surfactant products to address the most significant respiratory conditions affecting pediatric populations. In particular, in response to written guidance received in February 2010 from the FDA, we are performing a comprehensive preclinical program to potentially address the sole remaining issue that was identified in the April 2009 Complete Response Letter to gain Surfaxin approval. See “– Business Strategy Update.” There can be no assurance that our research and development projects (including the ongoing preclinical program for Surfaxin) 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 secure strategic alliances or obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in securing strategic alliances, raising additional capital, developing product candidates and obtaining regulatory approval and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.



As of March 31, 2010, we had cash and cash equivalents of \$24.2 million, which includes net proceeds of \$15.1 million (\$16.5 million gross) from a public offering that we completed in February 2010. As of May 7, 2010, neither the May 2008 CEFF nor the December 2008 CEFF was available to us because the closing market price of our common stock (\$0.47) was below the minimum price required (\$1.15 and \$0.60, respectively) to utilize the facility. If and when the CEFFs become available, we may potentially raise (subject to certain conditions, including minimum stock price and volume limitations) up to an aggregate of \$69.5 million. See, Note 5 – Stockholders' Equity, for details about our CEFFs.

As of March 31, 2010, our \$10.5 million loan with PharmaBio Development Inc (PharmaBio), the former strategic investment subsidiary of Quintiles Transnational Corp. (Quintiles), was classified as a current liability payable on April 30, 2010. On April 28, 2010, we completed a restructuring of the loan (\$10.6M at the time of restructuring) pursuant to a Payment Agreement and Loan Amendment dated April 27, 2010 (PharmaBio Agreement) that provided for (a) payment in cash of an aggregate of \$6.6 million, representing \$4.5 million in outstanding principal and \$2.1 million in accrued interest, (b) a maturity date extension for the remaining \$4 million principal amount under the loan, \$2 million of which now will be due and payable on July 30, 2010 and the remaining \$2 million of which will be due and payable on September 30, 2010, and (c) so long as we timely make each of the remaining principal payments on or before their respective due dates, no further interest will accrue on the outstanding principal amount. In addition, we agreed to maintain (i) at least \$10 million in cash and cash equivalents until payment of the first \$2 million installment is made on or before July 30, 2010, and (ii) at least \$8 million in cash and cash equivalents until the payment of the second \$2 million installment on or before September 30, 2010, after which the PharmaBio loan will be paid in full. Also under the PharmaBio Agreement, PharmaBio surrendered to us for cancellation warrants to purchase an aggregate of 2,393,612 shares of our common stock that we had issued previously to PharmaBio in connection with the PharmaBio loan and a previous offering of securities. See, “– Debt – Loan with PharmaBio Development, Inc.” Also, on April 30, 2010, we completed an offering of common stock and warrants to PharmaBio, resulting in gross proceeds of \$2.2 million (\$2.1 million net). See, “– Financings Pursuant to Common Stock Offerings – Financings under the 2008 Shelf Registration Statement.”

To meet our capital requirements, we continue to consider multiple strategic alternatives, including, but not limited to potential business alliances, commercial and development partnerships, additional financings and other similar opportunities, although there can be no assurance that we will take any further specific actions or enter into any transactions. Until such time as we secure the necessary capital, we plan to continue conserving our financial resources, predominantly by limiting investments in our pipeline programs.

## **Cash Flows**

As of March 31, 2010, we had cash and cash equivalents of \$24.2 million compared to \$15.7 million as of December 31, 2009, an increase of \$8.5 million. In February 2010, we completed a public offering of common stock and warrants resulting in net proceeds of \$15.1 million. Additionally, cash outflows before financings for the first quarter of 2010 consisted of \$5.3 million used for ongoing operating activities, a one-time payment of \$1.1 million to satisfy certain contractual cash severance obligations to our former President and Chief Executive Officer, and \$0.2 million used for debt service.

### Cash Flows Used in Operating Activities

Cash flows used in operating activities were \$6.4 million and \$7.5 million the three months ended March 31, 2010 and 2009, 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, fair value adjustment of common stock warrants, depreciation and changes in our accounts payable, accrued liabilities and receivables. Cash flows used in operating activities for the three months ended March 31, 2010 included a one-time payment of \$1.1 million to satisfy certain contractual cash severance obligations to our former President and Chief Executive Officer.

### Cash Flows Used in Investing Activities

Cash flows used in investing activities included purchases of equipment of \$0.1 million and \$0.1 million for the three months ended March 31, 2010 and 2009, respectively.

### Cash Flows from/(used in) Financing Activities

Cash flows from financing activities were \$14.9 million and \$1.7 million for the three months ended March 31, 2010 and 2009, respectively.

Cash flows from financing activities for the three months ended March 31, 2010 primarily included net proceeds of \$15.1 million from the February 2010 public offering, partially offset by principal payments on our equipment loan and capital lease obligations of \$0.2 million. See, “– Common Stock Offerings – Financings under the 2008 Shelf Registration Statement.” Cash flows used in financing activities for the three months ended March 31, 2009 included \$2.5 million from financings pursuant to our CEFFs, partially offset by \$0.8 million of principal payments under our equipment loan.

### **Committed Equity Financing Facilities (CEFFs)**

As of March 31, 2010, we had two CEFFs as follows: (i) the CEFF dated December 12, 2008 (December 2008 CEFF) and; (ii) the CEFF dated May 22, 2008 (May 2008 CEFF), which allow us, subject to minimum price requirements and volume limitations, 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. Under the December 2008 CEFF, as of March 31, 2010, we had 7.1 million shares potentially available for issuance (up to a maximum of \$17.7 million), provided that the volume weighted-average price of our common stock (VWAP) on each trading day during the draw-down period must be at least equal to the greater of (i) \$.60 or (ii) 90% of the closing price of our common stock on the trading day immediately preceding the draw down period (Minimum VWAP). Under the May 2008 CEFF, as of March 31, 2010, we had approximately 12.8 million shares potentially available for issuance (up to a maximum of \$51.7 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 2009 Annual Report on Form 10-K – “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility (CEFF)”. We anticipate using our CEFFs (at such times as our stock price is at a level above the CEFF minimum price requirement) to support our working capital needs and maintain cash availability in 2010.

To date, we have not used the CEFFs in 2010. As the current market price of our common stock is below the minimum price (\$0.60 and \$1.15) required by the CEFFs, neither CEFF is currently available. In 2009, we raised an aggregate of \$10.7 million from 10 draw-downs under our CEFFs throughout the year.

### **Common Stock Offerings**

Historically, we have funded, and expect that we may continue to fund, our business operations through various sources, including financings in the form of common stock offerings. In June 2008, we filed a universal shelf registration statement on Form S-3 (No. 333-151654) (2008 Shelf Registration Statement) 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.

### Financings under the 2008 Shelf Registration Statement

On April 27, 2010, we entered into a Securities Purchase Agreement with PharmaBio, as the sole purchaser, related to an offering of 4,052,312 shares of common stock and warrants to purchase an aggregate of 2,026,156 shares of common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.50 of a share of common stock, at an offering price of \$0.5429 per unit, representing the greater of (a) the volume-weighted average sale price (“VWAP”) per share of the common stock on The Nasdaq Global Market for the 20 trading days ending on April 27, 2010 and (b) the last reported closing price of \$0.5205 per share of the common stock on The Nasdaq Global Market on such date. The offering resulted in gross proceeds to us of \$2.2 million (\$2.1 million net). The warrants expire in April 2015 and generally will be exercisable beginning 181 days after the date of issuance, subject to an aggregate beneficial ownership limitation of 9.9%, at a price per share of \$0.7058, which represents a 30% premium to the VWAP for the 20 trading days ending on April 27, 2010. The exercise price and number of shares of common stock issuable on exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction. The exercise price and the amount and/or type of property to be issued upon exercise of the warrants will also be subject to adjustment if the Company engages in a “Fundamental Transaction” (as defined in the form of warrant). The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not available for the resale of the warrant shares, the holder may exercise on a cashless basis. The offering closed on April 30, 2010.

In February 2010, we completed a public offering of 27.5 million shares of our common stock and warrants to purchase 13.8 million shares of our common stock, sold as units, with each unit consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock, at a public offering price of \$0.60 per unit, resulting in gross proceeds to us of \$16.5 million (\$15.1 million net). The warrants expire in February 2015 and are exercisable, subject to an aggregate share ownership limitation, at a price per share of \$0.85. The exercise price and number of shares of common stock issuable on exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction. The exercise price and the amount and/or type of property to be issued upon exercise of the warrants will also be subject to adjustment if the Company engages in a “Fundamental Transaction” (as defined in the warrant agreement). The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not available for the resale of the warrant shares, the holder may exercise on a cashless basis.

As of March 31, 2010 and May 10, 2010, there was \$122.2 million and \$120.0 million, respectively, remaining available under the 2008 Shelf Registration Statement 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 PharmaBio Development Inc.*

As of March 31, 2010, our \$10.5 million loan with PharmaBio was classified as a current liability, payable on April 30, 2010. On April 27, 2010, we entered into the PharmaBio Agreement and on April 28, 2010, completed a restructuring of the loan (\$10.6M at the time of restructuring). The PharmaBio Agreement provided for (a) payment in cash of an aggregate of \$6.6 million, representing \$4.5 million in outstanding principal and \$2.1 million in accrued interest, (b) a maturity date extension for the remaining \$4 million principal amount under the loan, \$2 million of which now will be due and payable on July 30, 2010 and the remaining \$2 million of which will be due and payable on September 30, 2010, and (c) so long as we timely make each of the remaining principal payments on or before their respective due dates, no further interest will accrue on the outstanding principal amount. In addition, we agreed to maintain (i) at least \$10 million in cash and cash equivalents until payment of the first \$2 million installment is made on or before July 30, 2010, and (ii) at least \$8 million in cash and cash equivalents until the payment of the second \$2 million installment on or before September 30, 2010, after which the PharmaBio loan will be paid in full.

Also under the PharmaBio Agreement, PharmaBio surrendered to us for cancellation the following warrants to purchase an aggregate of 2,393,612 shares of our common stock that we had issued previously to PharmaBio in connection with the PharmaBio loan and a previous offering of securities: a warrant to purchase 850,000 shares of common stock, at \$7.19 per share expiring on November 3, 2014, a warrant to purchase 1,500,000 shares of common stock at \$3.58 per share expiring on October 26, 2013 and a warrant to purchase 43,612 shares of the Company’s common stock at \$6.875 per share expiring on September 19, 2010.

The PharmaBio Agreement also provided that we and PharmaBio would negotiate in good faith to potentially enter into a strategic arrangement under which PharmaBio would provide funding for a research collaboration between Quintiles and us relating to the possible research and development, and commercialization of two of our drug product candidates, Surfaxin LS and Aerosurf, for the prevention and treatment of RDS in premature infants. However, neither party is obligated to enter into any such arrangement except to the extent that the parties, in their individual and sole discretion, enter into definitive documents with respect thereto. Accordingly, there can be no assurances that any such arrangement or collaboration will be completed.

Also, on April 27, 2010, we entered into a Securities Purchase Agreement pursuant to which PharmaBio agreed to purchase 4,052,312 shares of our common stock and warrants to purchase an aggregate of 2,026,156 shares of our common stock, resulting in gross proceeds to us, on April 29, 2010, of \$2.2 million (\$2.1 million net). See, “ – Common Stock Offerings – Financing under the 2008 Shelf Registration Statement.”

At the present time, we are focused on securing appropriate strategic and financial resources to fund our research and development programs, comply with our financial covenants under the restructured PharmaBio loan, and pay the principal amount when due. Under our amended PharmaBio loan, PharmaBio holds a security interest in substantially all of our assets, including our proprietary assets and intellectual property. If we fail to comply with the cash covenants required under the restructuring, PharmaBio would have the right to declare all borrowings to be immediately due and payable. If we are unable to pay when due amounts owed to PharmaBio, whether at maturity or in connection with acceleration of the loan following a default, PharmaBio would have the right to proceed against the collateral securing the indebtedness.

To secure the necessary capital to achieve our objectives, we prefer to enter into strategic alliances, including potential business alliances, and commercial and development partnerships, including the potential collaboration with Quintiles. We are also considering other alternatives, including additional financings and other similar opportunities. However, there can be no assurance that we will achieve any strategic alliance or otherwise consummate any financing or other similar opportunities. If we are unable to secure the necessary capital to meet our covenants and financial commitments, we will be forced to potentially downsize our operations and implement further cutbacks in our program.

#### 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.). The right to draw under this Facility expired on November 30, 2008. As of March 31, 2010, approximately \$0.4 million was outstanding under the facility (\$0.4 million classified as current liabilities and \$36,000 as long-term liabilities).

In September 2008, we entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department), pursuant to which the Department made a loan to us from the Machinery and Equipment Loan Fund in the amount of \$500,000 (MELF Loan). As of March 31, 2010, approximately \$0.4 million was outstanding under the facility (\$0.1 million classified as current liabilities and \$0.3 million as long-term liabilities).

See, our 2009 Annual Report on Form 10-K – “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Equipment Financing Facilities.”

#### Contractual Obligations and Commitments

During the three-month period ended March 31, 2010, there were no material changes to our contractual obligations and commitments disclosures as set forth in our 2009 Annual Report on Form 10-K, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Contractual Obligations”, except as noted below.

In connection with the resignation in August 2009 of Robert J. Capetola, Ph.D., our former President, Chief Executive Officer and member of our Board of Directors, we entered into a separation agreement and general release (the "Separation Agreement") dated August 13, 2009, that provided, among other things, for periodic severance payments through the earlier of (i) May 3, 2010 (Severance Period) or (ii) the date, if ever, of a Corporate Transaction (defined below). Under the Separation Agreement, if a Corporate Transaction were to occur during the Severance Period, Dr. Capetola would become entitled to receive an additional severance payment of up to \$1,580,000; provided, however, such payment would be reduced by the sum of the aggregate cash severance amounts already paid under the Separation Agreement.

A "Corporate Transaction" was defined in the Separation Agreement to include one or more public or private financings that were completed during the Severance Period and resulted in cash proceeds (net of transaction costs) to us of at least \$20 million received during the Severance Period or within 90 calendar days thereafter. From August 13, 2009 through February 23, 2010, we raised approximately \$21.0 million of aggregate net proceeds, consisting of approximately \$5.9 million from financing transactions under our CEFs throughout the period and \$15.1 million from a public offering that was completed on February 23, 2010. As these transactions satisfied the criteria for a Corporate Transaction under the Separation Agreement, on March 3, 2010, we paid to Dr. Capetola an additional \$1.06 million (less withholding), representing \$1.58 million reduced by the sum of the cash severance amounts previously paid under the Separation Agreement, which totaled approximately \$0.52 million. At this time, our obligation to make periodic payments under the Separation Agreement has been satisfied and no further payments are due to Dr. Capetola.

The full text of the Separation Agreement is attached to our Current Report on Form 8-K that we filed with the SEC on August 19, 2009. *See also*, "Item 11- Executive Compensation – Resignation of our President and Chief Executive Officer," in our Amendment No. 1 to our 2009 Annual Report on Form 10-K that we filed with the SEC on April 30, 2010 (2009 Form 10-K/A).

### **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.

In connection with the preparation of this Amendment No. 1, our Interim Chief Executive Officer and our Chief Financial Officer evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2010. In making this evaluation, they considered the material weakness related to the classification of warrants discussed below. Solely as a result of the material weakness, our Interim Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of March 31, 2010.

#### *Management's Report on our Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) promulgated under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. In connection with this Amendment No. 1, management, including our Chief Executive Officer and Chief Financial Officer, reassessed the effectiveness of our internal control over financial reporting as of March 31, 2010. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. This evaluation identified a material weakness in our internal control regarding our process and procedures related to the initial classification and subsequent accounting of registered warrants as liabilities or equity instruments. This material weakness in our internal controls resulted in the restatement of our 2009 financial statements and our quarterly report for the period ended March 31, 2010. Accordingly, we did not maintain effective internal control over financial reporting as of March 31, 2010, based on the COSO criteria.

#### Changes in internal controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) under the Exchange Act that occurred during the quarter ended March 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **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 discussed in this Form 10-Q, see the risks and uncertainties discussed in our 2009 Annual Report on Form 10-K and our 2009 Form 10-K/A, including the "Risk Factors" section contained in our 2009 Annual Report on Form 10-K.

**The terms of our indebtedness may impair our ability to conduct our business.**

Our capital requirements have been funded in part by the loan from PharmaBio, with respect to which we completed a restructuring on April 28, 2010. Under the restructuring, we paid in cash \$6.6 million of the total outstanding (\$10.6 million at the time of restructuring), representing \$4.5 million in outstanding principal and \$2.1 million in accrued interest. Of the remaining \$4 million principal amount under the loan, \$2 million will now be due and payable on July 30, 2010 and the balance of \$2 million will be due and payable on September 30, 2010. If we make our payments on time, no further interest will accrue on the outstanding principal amount. The PharmaBio loan is secured by substantially all of our assets, including our proprietary technologies, and contains a number of covenants and restrictions that, with certain exceptions, restricts our ability to, among other things, incur additional indebtedness, borrow money or issue guarantees, use assets as security in other transactions, and sell assets to other companies. In connection with the restructuring we agreed to an additional covenant to maintain (i) at least \$10 million in cash and cash equivalents until payment of the first \$2 million installment is made on or before July 30, 2010, and (ii) at least \$8 million in cash and cash equivalents until the payment of the second \$2 million installment on or before September 30, 2010, after which the PharmaBio loan will be paid in full. In order to comply with these cash covenants and to have sufficient working capital to make payment of the remaining principal amount and continue operate our business, we will likely need to secure sources of additional capital. If we are unable to secure additional sources of capital, we will be forced to further reduce our cash outflows and limit our investments in our research and development programs. If we fail to comply with the cash covenants required under the restructuring, PharmaBio would have the right to declare all borrowings to be immediately due and payable. If we are unable to pay when due amounts owed to PharmaBio, whether at maturity or in connection with acceleration of the loan following a default, PharmaBio would have the right to proceed against the collateral securing the indebtedness.

Under the restructuring, PharmaBio agreed to negotiate in good faith to potentially enter into a strategic arrangement under which PharmaBio would provide funding for a research collaboration between Quintiles and us relating to the possible research and development, and commercialization of two of our drug product candidates, Surfaxin LS and Aerosurf, for the prevention and treatment of RDS in premature infants. In that event, it is possible that the remaining principal payments might in the future be restructured, deferred or otherwise satisfied without further cash outlays. However, neither party is obligated to enter into any such arrangement and there can be no assurances that any such arrangement will be completed or that we will be successful in securing the additional capital required to continue our operations.

**The restatement of our historical financial statements has already consumed a significant amount of our time and resources and may have a material adverse effect on our business and stock price.**

As described earlier, we have restated our consolidated financial statements. The restatement process was highly time and resource-intensive and involved substantial attention from management and significant legal and accounting costs. Although we have now completed the restatement, we cannot guarantee that we will have no inquiries from the SEC or The NASDAQ Capital Market® (“Nasdaq Capital Market”) regarding our restated financial statements or matters relating thereto.

Any future inquiries from the SEC as a result of the restatement of our historical financial statements will, regardless of the outcome, likely consume a significant amount of our resources in addition to those resources already consumed in connection with the restatement itself.

Further, many companies that have been required to restate their historical financial statements have experienced a decline in stock price and stockholder lawsuits related thereto.

**If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting.**

We are required by the SEC to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We are likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses in those internal controls.

As described elsewhere in this Amendment No. 1, in connection with the restatement process, we identified a material weakness with regard to accounting for warrant instruments in our internal control over financial reporting, specifically with regard to our prior interpretation of ASC 815, as it related to the initial classification and subsequent accounting of registered warrants as either liabilities or equity instruments dating back to May 2009. Upon a reassessment of those financial instruments, in light of GAAP as currently interpreted, we determined that we should have accounted for certain warrant instruments as debt instead of equity. Given this material weakness with regard to warrants, management was unable to conclude that we maintained effective internal control over financial reporting as of March 31, 2010.

Since the determination regarding this material weakness, we plan to devote significant effort and resources to the remediation and improvement of our internal control over financial reporting. While we have processes to identify and intelligently apply developments in accounting, we plan to enhance these processes to better evaluate our research and understanding of the nuances of increasingly complex accounting standards. Our plans include the following: enhanced access to accounting literature, research materials and documents; and increased communication among our legal and finance personnel and third party professionals with whom to consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time and we can offer no assurance that these initiatives will ultimately have the intended effects. Any failure to maintain such internal controls could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and Nasdaq, we could face severe consequences from those authorities. In either case, there could result a material adverse affect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

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

During the three months ended March 31, 2010, we did not issue any unregistered shares of common stock pursuant to the exercise of outstanding warrants and options. There were no stock repurchases during the three months ended March 31, 2010.

For disclosure on our working capital restrictions under our PharmaBio loan, please refer to “Liquidity and Capital Resources – Overview.”

## **ITEM 6. EXHIBITS**

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



**SIGNATURES**

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

Discovery Laboratories, Inc.  
(Registrant)

Date: November 12, 2010

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

Date: November 12, 2010

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

## INDEX TO EXHIBITS

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

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Amended and Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery), dated December 9, 2009.	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 9, 2009.
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	Amended and Restated By-Laws of Discovery, as amended effective September 3, 2009.	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on September 4, 2009.
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 PharmaBio (formerly 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.
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 by and between Discovery and Capital Ventures International	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.

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Exhibit No.	Description	Method of Filing
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 Stock Purchase Warrant issued in May 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.
4.12	Form of Stock Purchase Warrant issued in February 2010	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 18, 2010.
4.13	Warrant Agreement, dated as of April 30, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
10.1	Payment Agreement and Loan Amendment (amending the Second Amended and Restated Loan Agreement, dated as of December 10, 2001, amended and restated as of October 25, 2006) dated April 27, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 1.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
10.2	Third Amended Promissory Note dated April 27, 2010 (amending and restating the Second Amended Promissory Note dated as of October 25, 2006), payable to PharmaBio	Incorporated by reference to Exhibit 1.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
10.3*	Retention Letter dated May 4, 2010 by and between Robert Segal, M.D., F.A.C.P., and Discovery	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on May 10, 2010.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Incorporated by reference to Exhibit 31.1 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on May 10, 2010.
31.2	Certification of Chief Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Incorporated by reference to Exhibit 31.2 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on May 10, 2010.
31.3	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.4	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Incorporated by reference to Exhibit 32.1 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on May 10, 2010.
32.2	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.

\* A management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report pursuant to Item 15(b) of Form 10-K.

## CERTIFICATIONS

I, W. Thomas Amick, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q of Discovery Laboratories, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2010

/s/ W. Thomas Amick

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

## CERTIFICATIONS

I, John G. Cooper, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q of Discovery Laboratories, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2010

/s/ John G. Cooper

John G. Cooper  
President and Chief Financial Officer

## CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Amendment No. 1 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2010 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2010

/s/ W. Thomas Amick

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W. Thomas Amick

Chairman of the Board and Chief Executive Officer

/s/ John G. Cooper

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John G. Cooper

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.