

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

FORM 10-Q

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

For the quarterly period ended June 30, 2011

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 August 5, 2011, 24,234,912 shares of the registrant's common stock, par value \$0.001 per share, were outstanding.

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Unless the context otherwise requires, all references to “we,” “us,” “our,” and the “Company” include Discovery Laboratories, Inc., and its wholly owned, presently inactive subsidiary, Acute Therapeutics, Inc.

## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations; plans regarding our efforts to gain U.S. regulatory approval for our lead products, Surfaxin<sup>®</sup> (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants; plans regarding our efforts to gain approval in the United States and the European Union for Afectair<sup>™</sup>; the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our KL<sub>4</sub> surfactant technology and for our proprietary drug delivery medical devices, including our capillary aerosolization and proprietary patient interface technologies, including planning for and timing of any clinical trials, if required, and potential development milestones; the development of financial, clinical, manufacturing and distribution plans related to the potential commercialization of our product candidates, if approved; and plans regarding potential strategic alliances and other collaborative arrangements with pharmaceutical companies and others to develop, manufacture and market our products.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of the risks and uncertainties include, but are not limited to:

- risks related generally to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug product and medical device candidates, including our lead products that we are developing to address respiratory distress syndrome (RDS) in premature infants: Surfaxin for the prevention of RDS, Aerosur<sup>®</sup> (our initial aerosolized KL<sub>4</sub> surfactant), a key component of which is Afectair<sup>™</sup> (our proprietary patient interface technology) and Surfaxin LS<sup>™</sup> (our initial lyophilized KL<sub>4</sub> surfactant);
- the risk that we and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;
- the risk that the FDA will not be satisfied with the results of our efforts to (i) finally validate our optimized fetal rabbit biological activity test (BAT), (ii) demonstrate that the BAT has the ability to adequately reflect the biological activity of Surfaxin throughout its shelf life and to discriminate biologically active from inactive Surfaxin drug product, and (iii) demonstrate the comparability of drug product used in the Surfaxin Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use through prospectively-designed, side-by-side preclinical studies (i.e., concordance studies) using the optimized BAT and the well-established preterm lamb model of RDS;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;

- risks relating to the rigorous regulatory approval processes, including pre-filing activities, required for approval of any drug, combination drug-device product or medical device that we may develop, whether independently, with strategic development partners or pursuant to collaboration arrangements;
- the risk that the FDA may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities;
- the risk that we may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin;
- the risk that the FDA or the European Medicines Agency (EMA) may not grant market authorization for Afectair, if at all, within the anticipated time frame;
- risks, if we succeed in gaining approval of Surfaxin or Afectair and our other product candidates, relating to our lack of marketing and distribution capabilities, which we will have to develop internally or secure through third-party strategic alliances and/or marketing alliances and/or distribution arrangements, that could require us to give up rights to our drug products and drug product candidates;
- risks, if we succeed in gaining approval of Surfaxin and Afectair and our other product candidates, that reimbursement and health care reform may adversely affect us or that our products will not be accepted by physicians, patients and others in the medical community;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- risks relating to our research and development activities, which involve time-consuming and expensive preclinical studies and other efforts, and potentially multiple clinical trials, which may be subject to potentially significant delays or regulatory holds, or may fail, and which must be conducted using sophisticated and extensive analytical methodologies, including an acceptable BAT, if required, as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities;
- risks relating to our ability to develop and manufacture drug products based on our KL<sub>4</sub> surfactant technology, and drug-device combination products and medical devices based on our capillary aerosolization and patient interface technologies, for clinical studies and, if approved, for commercialization of our product candidates;
- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers and assemblers;
- the risk that we, our contract manufacturers or any of our third-party suppliers may encounter problems or delays in manufacturing or assembling drug products, drug product substances, capillary aerosolization devices, patient interface adapters and related components and other materials on a timely basis or in an amount sufficient to support our development efforts and, if our products are approved, commercialization;
- the risk that we may be unable to identify potential strategic partners or collaborators with whom we can develop and, if approved, commercialize our products in a timely manner, if at all;
- the risk that we or our strategic partners or collaborators will not be able to attract or maintain qualified personnel;

- the risk that market conditions, the competitive landscape or other factors may make it difficult to launch and profitably sell our products, if approved;
- the risk that we may not be able to raise additional capital or enter into strategic alliances or collaboration agreements (including strategic alliances for development or commercialization of our drug products and combination drug-device products);
- risks that the unfavorable credit environment will adversely affect our ability to fund our activities, that our share price will not reach or remain at the price level necessary for us to access capital under our Committed Equity Financing Facility (CEFF), that the CEFF may expire before we are able to access the full dollar amount potentially available thereunder, and that additional equity financings could result in substantial equity dilution;
- the risk that, although we successfully regained compliance in early 2011 with the continued listing requirements of The Nasdaq Capital Market® (Nasdaq), we will be unable to maintain compliance with the listing requirements in the future, including without limitation those relating to minimum bid price, market capitalization and stockholders equity, which could increase the probability that our stock will be delisted from Nasdaq, which could cause our stock price to decline;
- risks related to our need for significant additional capital to continue our planned research and development activities and continue operating as a going concern, which if funded through equity financings, could result in equity dilution;
- the risks that we may be unable to maintain and protect the patents and licenses related to our products and that other companies may develop competing therapies and/or technologies;
- the risks that we may become involved in securities, product liability and other litigation and that our insurance may be insufficient to cover costs of damages and defense;
- the risks that we will be unable to attract and retain key employees in a competitive market for skilled personnel, which could affect our ability to develop and market our products; and
- other risks and uncertainties detailed in our most recent Annual Report on Form 10-K and other filings with the Securities and Exchange Commission, and any amendments thereto, and in any documents incorporated by reference in this report.

Pharmaceutical, biotechnology and medical technology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products, and may never become profitable.

The forward-looking statements contained in this report or the documents incorporated by reference herein speak only of their respective dates. Factors or events that could cause our actual results to differ may emerge from time to time and it is not possible for us to predict them all. Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

## PART I - FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

## Consolidated Balance Sheets

(in thousands, except per share data)

	June 30, 2011	December 31, 2010
	(Unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 21,542	\$ 10,211
Prepaid expenses and other current assets	299	285
Total Current Assets	21,841	10,496
Property and equipment, net	2,839	3,467
Restricted cash	400	400
Other assets	168	174
Total Assets	25,248	\$ 14,537
<b>LIABILITIES &amp; STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 1,986	\$ 1,685
Accrued expenses	2,973	3,286
Common stock warrant liability	10,021	2,469
Equipment loans and capitalized leases, current portion	93	136
Total Current Liabilities	15,073	7,576
Equipment loans and capitalized leases, non-current portion	260	301
Other liabilities	708	634
Total Liabilities	16,041	8,511
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized; no shares issued or outstanding	-	-
Common stock, \$0.001 par value; 50,000 shares authorized; 24,256 and 13,822 shares issued, 24,235 and 13,801 shares outstanding	24	14
Additional paid-in capital	400,605	385,521
Accumulated deficit	(388,368)	(376,455)
Treasury stock (at cost); 21 shares	(3,054)	(3,054)
Total Stockholders' Equity	9,207	6,026
Total Liabilities & Stockholders' Equity	\$ 25,248	\$ 14,537

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenue	\$ 201	\$ –	\$ 582	\$ –
Expenses:				
Research and development	4,615	4,363	9,235	8,496
General and administrative	1,966	1,865	3,786	4,797
Total expenses	<u>6,581</u>	<u>6,228</u>	<u>13,021</u>	<u>13,293</u>
Operating loss	(6,380)	(6,228)	(12,439)	(13,293)
Change in fair value of common stock warrant liability	(1,693)	5,519	535	6,749
Other income / (expense):				
Interest and other income	3	5	7	24
Interest and other expense	(6)	(89)	(16)	(331)
Other income / (expense), net	<u>(3)</u>	<u>(84)</u>	<u>(9)</u>	<u>(307)</u>
Net loss	<u>\$ (8,076)</u>	<u>\$ (793)</u>	<u>\$ (11,913)</u>	<u>\$ (6,851)</u>
Net loss per common share –Basic and diluted	\$ (0.34)	\$ (0.07)	\$ (0.56)	\$ (0.69)
Weighted average number of common shares outstanding – basic and diluted	24,027	10,695	21,086	9,942

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

(in thousands)

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (11,913)	\$ (6,851)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	644	864
Stock-based compensation and 401(k) match	599	914
Fair value adjustment of common stock warrants	(535)	(6,749)
(Gain) / Loss on sale of equipment	10	(16)
<b>Changes in:</b>		
Prepaid expenses and other current assets	(14)	(150)
Accounts payable	301	(59)
Accrued expenses	(313)	320
Other assets	6	2
Other liabilities and accrued interest on loan payable	73	(1,994)
Net cash used in operating activities	<u>(11,142)</u>	<u>(13,719)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(26)	(73)
Net cash used in investing activities	<u>(26)</u>	<u>(73)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of securities, net of expenses	22,583	26,248
Principal payments under loan payable	–	(4,500)
Principal payments under equipment loan and capital lease obligations	(84)	(377)
Net cash provided by financing activities	<u>22,499</u>	<u>21,371</u>
Net increase in cash and cash equivalents	11,331	7,579
Cash and cash equivalents – beginning of period	10,211	15,741
Cash and cash equivalents – end of period	<u>\$ 21,542</u>	<u>\$ 23,320</u>
<b>Supplementary disclosure of cash flows information:</b>		
Interest paid	\$ 11	\$ 2,104
<b>Non-cash transactions:</b>		
Equipment acquired through capitalized lease	–	48



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

### **Note 1 – The Company and Basis of Presentation**

#### **The Company**

Discovery Laboratories, Inc. (referred to as “we,” “us,” or the “Company”) is a specialty biotechnology company dedicated to improving the standard of respiratory critical care through its proprietary KL<sub>4</sub> surfactant and aerosol drug delivery technologies. Surfactants are produced naturally in the lungs and are essential for breathing. Our novel proprietary KL<sub>4</sub> surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol and lyophilized formulations. Our proprietary capillary aerosolization and patient interface technologies are being developed to enable delivery of our KL<sub>4</sub> surfactant or other therapies for critical care and pulmonary applications. We believe that our proprietary KL<sub>4</sub> surfactant technology makes it possible, for the first time, to develop a significant pipeline of respiratory critical care products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

We are developing our lead KL<sub>4</sub> surfactant drug products, Surfaxin® (lucinactant), Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting neonatal populations. Our research and development efforts are currently focused on the management of respiratory distress syndrome (RDS) in premature infants. We filed a New Drug Application (NDA) for Surfaxin for the prevention of RDS in premature infants. The safety and efficacy of Surfaxin for the prevention of RDS in premature infants has previously been demonstrated in a large, multinational Phase 3 clinical program. We received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in April 2009 (2009 Complete Response Letter). We believe that a key remaining step to potentially gain U.S. marketing approval is to satisfy the FDA as to the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit biological activity test (BAT). We have completed a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT and are finalizing our data submission. We believe that we remain on track to file a Complete Response for Surfaxin in the third quarter of 2011, which could lead to the potential approval of Surfaxin for the prevention of RDS in premature infants in the first quarter 2012.

We are developing Surfaxin LS and Aerosurf for the prevention and/or treatment of RDS in premature infants in both the United States and other major markets worldwide. Surfaxin LS is our initial lyophilized (freeze-dried) KL<sub>4</sub> surfactant that is resuspended to liquid form prior to use and is intended to improve ease of use for healthcare practitioners and potentially eliminate the need for cold-chain storage. Aerosurf is our initial aerosolized KL<sub>4</sub> surfactant that is administered through less-invasive means and is being developed to potentially obviate the need for endotracheal intubation and conventional mechanical ventilation. We believe that Aerosurf, if approved, will address a significant unmet medical need by providing practitioners with the alternative of administering surfactants to infants at risk for RDS through less invasive means, which may result in a potentially significant increase in the number of infants who will benefit from surfactant therapy.

Aerosurf combines our KL<sub>4</sub> surfactant with our aerosol delivery technologies: our proprietary capillary aerosolization device and our novel patient interface adapters. Our capillary aerosolization device has been initially designed to produce high quality, low-velocity aerosolized KL<sub>4</sub> surfactant for intra-pulmonary delivery for the prevention and/or treatment of RDS in premature infants. In developing our proprietary patient interface technology for Aerosurf, we focused on developing a patient interface and related componentry suitable for use with our capillary aerosolization technology in neonatal intensive care units (NICUs). We have also explored the potential utility of developing our patient interface technology to potentially benefit all patients receiving ventilatory support who require aerosolized medicines in a critical care setting. With research provided by an independent market research firm, we recently concluded a market assessment of our patient interface adapters and announced our intention to develop, and seek market authorization in the United States and the European Union for the series of our patient interface adapters under the trade name Afectair.

Afectair is a series of novel patient interface adapters and related componentry based on our proprietary patient interface technology that simplifies the effective delivery of any aerosolized medication to critical-care patients requiring ventilatory support by introducing aerosolized medications directly at the patient interface and minimizing the number of connections to the ventilatory circuitry. We are developing a regulatory plan to potentially gain marketing authorization for Afectair in the United States and the European Union and, if approved, believe that we could be in a position to initiate the commercial introduction of Afectair in both markets in 2012.

In addition to our lead products, as our resources permit, 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 conducted research and development activities with our KL<sub>4</sub> surfactant to potentially address acute lung injury (ALI) and cystic fibrosis and in the future may conduct further research and development activities to potentially address other diseases of the lung.

An important priority continues to be 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. We are engaged in discussions with potential strategic partners who potentially could provide development and commercial expertise as well as financial resources. We also intend to consider potential additional financings and other similar transactions to meet our capital requirements and continue to fund our operations. There can be no assurance, however, that we will successfully conclude any strategic alliance, financing or other similar transaction. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL<sub>4</sub> surfactant and aerosol drug delivery technologies and support our operations, we will continue to focus on our RDS programs, primarily Surfaxin, and Afectair, and conserve our resources, predominantly by curtailing and pacing investments in our other 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 and six months ended June 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. 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, 2010 (2010 Form 10-K) that we filed with the Securities and Exchange Commission (SEC) on March 31, 2011, as amended on April 29, 2011.

### **Note 2 – Liquidity Risks and Management’s Plans**

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

Our future capital requirements depend upon many factors, including (i) the success of our efforts to file the Complete Response for Surfaxin and potentially to gain regulatory approvals for Surfaxin in the United States and for Afectair in the United States and Europe, (ii) 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, and (iii) the success of our efforts to raise capital through financings and other transactions. We believe that anticipated revenue from the commercial introduction of Surfaxin and/or Afectair, if approved, could serve as a potential non-dilutive source of funds to support our research and development activities in the future. We also believe that our ability to successfully enter into meaningful strategic alliances will likely improve if we are able to gain regulatory approvals for Surfaxin and advance our Surfaxin LS and Aerosurf programs towards initiation of clinical trials. In addition to seeking strategic alternatives, including without limitation potential business alliances, commercial and development partnerships, and other similar opportunities, we continue to consider potential additional financings and other similar transactions to meet our capital requirements and continue to fund our operations. Even if we succeed in gaining regulatory approvals for, and subsequently commercializing, Surfaxin and Afectair and our other product candidates; in securing strategic alliances; and in raising additional capital to support our research and development activities as needed, we may never achieve sufficient sales revenue to achieve or maintain profitability.

There can be no assurance that that products we develop, include Surfaxin and Afectair, will obtain necessary regulatory approval, that any approved product will be commercially viable, that we will be able to secure strategic partners or collaborators to support and provide expert advice to guide our activities, that our research and development activities will be successful, that any CEFF or other facility will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL<sub>4</sub> surfactant and aerosol drug delivery technologies and fund our operations, we will continue to limit investment in our pipeline programs. In 2011, we plan to continue to manage our expenditures and focus our financial resources on our RDS programs, primarily in support of the potential approval of Surfaxin and Afectair.

As of June 30, 2011, we had cash and cash equivalents of \$21.5 million. We also have a CEFF, which could allow us, at our discretion, to raise capital (subject to certain conditions, including minimum stock price and volume limitations) at a time and in amounts deemed suitable for us to support our business plans. Based on the closing market price of our common stock on August 5, 2011 (\$2.20) and assuming that all available shares are issued, the potential availability under our CEFF is approximately \$2.6 million. In addition, in connection with our February 2011 public offering, we issued 15-month warrants to purchase our five million shares of our common stock at an exercise price of \$2.94 (15-month warrants). If the market price of our common stock should exceed \$2.94 at any time prior to May 2012 (the expiration date of the 15-month warrants), we potentially could raise up to an additional \$14.7 million in proceeds if the holders determine (in their discretion) to exercise the 15-month warrants and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants. See, Note 4 – “Stockholders’ Equity – Committed Equity Financing Facility (CEFF).” During the first quarter of 2011, we raised aggregate gross proceeds of \$24.5 million, including \$23.5 million (\$21.6 million net) from a public offering in February 2011 and \$1.0 million from a financing under our CEFF in January 2011. In addition, in 2011, we have received \$0.6 million under a Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health to support the development of aerosolized KL<sub>4</sub> surfactant for RDS.

### **Note 3 – Accounting Policies and Recent Accounting Pronouncements**

#### Accounting policies

There have been no changes to our critical accounting policies since December 31, 2010. For more information on critical accounting policies. See, Note 3 – “Summary of Significant Accounting Policies and Recent Accounting Pronouncements” to the consolidated financial statements included in our 2010 Form 10-K. Readers are encouraged to review those disclosures in conjunction with the review of this Quarterly Report on Form 10-Q.

#### Net loss per common share

Basic net loss per common share is computed by dividing the net loss by the weighted average number of common shares outstanding for the periods. As of June 30, 2011 and 2010, 14.0 million and 5.4 million shares of common stock, respectively, were potentially issuable upon the exercise of certain stock options and warrants. There also were 130,000 and 24,300 shares under unvested restricted stock awards (RSAs) outstanding as of June 30, 2011 and 2010, respectively. Due to our net loss, the potentially issuable shares and RSAs 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.

#### Recent accounting pronouncements

In October 2009, the Financial Accounting Standards Board (FASB) issued amendments to the accounting and disclosure guidance for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010, modify the criteria for recognizing revenue in multiple element arrangements and the scope of what constitutes a non-software deliverable. We adopted this guidance prospectively on January 1, 2011 and the adoption had no impact on our consolidated financial statements. The potential future impact of the adoption of these amendments will depend on the nature of any new arrangements that we enter into in the future.

#### **Note 4 – Stockholders' Equity**

##### Registered Public Offerings

On February 22, 2011, we completed a registered public offering of 10 million shares of our common stock, 15-month warrants to purchase five million shares of our common stock, and five-year warrants to purchase five million shares of our common stock. The securities were sold as units, with each unit consisting of one share of common stock, a 15-month warrant to purchase one half share of common stock, and a five-year warrant to purchase one half share of common stock, at a public offering price of \$2.35 per unit, resulting in gross proceeds to us of \$23.5 million (\$21.6 million net). The 15-month warrants expire in May 2012 and are exercisable at a price per share of \$2.94. The five-year warrants expire in February 2016 and are exercisable at a price per share of \$3.20. The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not otherwise available for the resale of the warrant shares, the holder may exercise on a cashless basis. The exercise price and number of shares or type of property issuable upon exercise of the warrants are subject to customary adjustments in the event of corporate events (as described in the warrants). In addition, the exercise price of the five-year warrants is subject to adjustment if we issue or sell common stock or securities convertible into common stock (in each case, subject to certain exceptions) at a price (determined as set forth in the warrant) that is less than the exercise price of the warrant.

##### Committed Equity Financing Facility (CEFF)

As of June 30, 2011, we had one Committed Equity Financing Facility dated June 11, 2010 (CEFF) with Kingsbridge Capital Limited (Kingsbridge). Under the CEFF, Kingsbridge is committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFF allows us at our discretion to raise capital for a period of three years ending June 11, 2013, at the time and in amounts deemed suitable to us. Two prior CEFFs, dated May 22, 2008 and December 12, 2008, expired in June 2011 and February 2011, respectively. We are not obligated to utilize any of the funds available under the CEFF. Our ability to access funds available under the CEFF is subject to certain conditions, including stock price and volume limitations. See, in our 2010 Form 10-K, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs)" for a detailed description of our CEFF.

As of June 30, 2011, there were approximately 1.3 million shares potentially available for issuance (up to a maximum of \$32.6 million) under the CEFF, provided that the volume-weighted average price per share of our common stock (VWAP) on each trading day must be at least equal to a price that we designate in the draw down notice, which may be either a price that we specify, but not less than \$0.20 per share, or 90% of the closing market price on the trading day preceding the first day of the draw down. Based on the closing market price of our common stock on August 5, 2011 (\$2.20) and assuming that all available shares are issued, the potential availability under our CEFF is approximately \$2.6 million.

We anticipate using our CEFF (when available) to support our working capital needs and maintain cash availability in 2011.

In January 2011 we completed a financing under our the CEFF, resulting in gross proceeds of \$1.0 million from the issuance of 314,179 shares of our common stock at an average price per share, after applicable fees and discounts, of \$3.16.

#### **Note 5 – Fair Value of Financial Instruments**

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, as follows:

- 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 Accounting Standards Codification (ASC) Topic 820 – “Fair Value Measurements and Disclosures.”
- 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

The table below categorizes assets and liabilities measured at fair value on a recurring basis as of June 30, 2011:

	Fair Value	Fair value measurement using		
	June 30, 2011	Level 1	Level 2	Level 3
<b>Assets:</b>				
Money Market	\$ 6,690	\$ 6,690	\$ –	\$ –
Certificate of Deposit	400	400	–	–
<b>Total Assets</b>	<b>\$ 7,090</b>	<b>\$ 7,090</b>	<b>\$ –</b>	<b>\$ –</b>
<b>Liabilities:</b>				
Common stock warrant liability	\$ 10,021	\$ –	\$ –	\$ 10,021

The table below summarizes the activity of Level 3 inputs measured on a recurring basis for the quarter ended June 30, 2011:

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2010	\$ 2,469
Issuance of common stock warrants	8,087
Change in fair value of common stock warrant liability	(535)
Balance at June 30, 2011	<u>\$ 10,021</u>

**Note 6 – Common Stock Warrant Liability**

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC Topic 815 – “Derivatives and Hedging — Contracts in Entity’s Own Equity,” as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

The registered warrants that we issued in our May 2009 and February 2010 public offerings generally provide that, in the event a related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. Notwithstanding the availability of cashless exercise, under generally accepted accounting principles, these registered warrants are deemed to be subject to potential net cash settlement and must be classified as derivative liabilities because (i) under the federal securities laws, it may not be within our absolute control to provide freely-tradable shares upon exercise of the warrants in all circumstances, and (ii) the warrant agreements do not expressly provide that there is no circumstance in which we may be required to effect a net cash settlement of the warrants (all other outstanding registered warrants that we have issued contain this language). The applicable accounting principles do not allow for an evaluation of the likelihood that an event would result in a cash settlement. Accordingly, in compliance with ASC Topic 815, the May 2009 and February 2010 warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using the Black-Scholes option pricing model.

The five-year warrants that we issued in February 2011 (February 2011 five-year warrants) contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the February 2011 five-year warrants. Due to the nature of the anti-dilution provisions, to comply with ASC Topic 815, these warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model.

Selected terms and estimated fair value of warrants accounted for as derivative liabilities at June 30, 2011 are as follows:

Issuance Date	Number of Warrant Shares Issuable	Exercise Price	Warrant Expiration Date	Fair Value of Warrants (in thousands)	
				Issuance Date	June 30, 2011
5/13/2009	466,667	\$ 17.25	5/13/2014	\$ 3,360	\$ 399
2/23/2010	916,669	12.75	2/23/2015	5,701	926
2/22/2011	5,000,000	3.20	2/22/2016	8,087	8,696

Changes in the estimated fair value of warrants classified as derivative liabilities are reported in the Consolidated Statement of Operations as the "Change in fair value of common stock warrants."

#### 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.

	June 30, 2011	June 30, 2010
Expected volatility	112%	99%
Expected term	4.9 years	4.7 years
Risk-free interest rate	1.47%	1.7%
Expected dividends	–	–

The total employee stock-based compensation for the three and six months ended June 30, 2011 and 2010 was as follows:

(in thousands)	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2011	2010	2011	2010
Research & Development	\$ 73	\$ 127	\$ 136	\$ 294
General & Administrative	110	277	228	509
Total	\$ 183	\$ 404	\$ 364	\$ 803

As of June 30, 2011, there was \$0.6 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under our 2007 Long-Term Incentive Plan. That cost is expected to be recognized over a weighted-average vesting period of six months for stock options and 1.3 years for restricted stock awards.

#### Note 8 – Subsequent Events

We evaluated all events or transactions that occurred after June 30, 2011 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 as noted below:

Effective July 31, 2011, David L. Lopez, Esq., C.P.A. resigned his position as our Executive Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer. We entered into a separation agreement and general release with Mr. Lopez providing for (1) immediate payment of his accrued and unpaid salary and vacation pay through July 31, 2011; (2) the right to continue to hold a restricted stock award (“RSA”) for 15,000 shares, subject to continued vesting in accordance with the terms and conditions of his RSA without any requirement that he be actively providing Service (as defined in the RSA); (3) reimbursement of COBRA medical and insurance premiums for a period of up to 18 months depending on the circumstances; and (4) reimbursement of up to \$10,000 for use of outplacement services if Mr. Lopez has not secured full time employment as a practicing attorney or corporate professional by May 1, 2012. On February 1, 2012, (i) Mr. Lopez will pay any outstanding principal and accrued interest on a promissory note issued to us in 2001 (as of June 30, 2011, the outstanding aggregate principal amount of the Note was \$171,952), and (ii) we will pay Mr. Lopez \$400,000 in separation pay. If Mr. Lopez fails to pay the Note on or prior to February 1, 2012, we will reduce the separation pay by the amount due under the Note and the Note shall be deemed to be paid in full. In addition, effective August 4, 2011, Mr. Lopez agreed to forfeit all outstanding options held by him that were granted pursuant to the 2007 Plan. If not forfeited, the options would have expired 90 days following the effective date of his resignation.

#### ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks and uncertainties. You should review the “Forward-Looking Statements” section of this Quarterly Report on Form 10-Q, as well as the “Risk Factors” section of our Annual Report on Form 10-K and other filings with the Securities and Exchange Commission (SEC), and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.*

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.

## OVERVIEW

Discovery Laboratories, Inc. (referred to as “we,” “us,” or the “Company”) is a specialty biotechnology company dedicated to improving the standard of respiratory critical care through its proprietary KL<sub>4</sub> surfactant and aerosol drug delivery technologies. Surfactants are produced naturally in the lungs and are essential for breathing. Our novel proprietary KL<sub>4</sub> surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol and lyophilized formulations. Our proprietary capillary aerosolization and patient interface technologies are being developed to enable delivery of our KL<sub>4</sub> surfactant or other therapies for critical care and pulmonary applications. We believe that our proprietary KL<sub>4</sub> surfactant technology makes it possible, for the first time, to develop a significant pipeline of respiratory critical care products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

We are developing our lead KL<sub>4</sub> surfactant drug products, Surfaxin® (lucinactant), Surfaxin LS™ and Aerosurf®, to address the most significant respiratory conditions affecting neonatal populations. Our research and development efforts are currently focused on the management of respiratory distress syndrome (RDS) in premature infants. We filed a New Drug Application (NDA) for Surfaxin for the prevention of RDS in premature infants. The safety and efficacy of Surfaxin for the prevention of RDS in premature infants has previously been demonstrated in a large, multinational Phase 3 clinical program. We received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in April 2009 (2009 Complete Response Letter). We believe that a key remaining step to potentially gain U.S. marketing approval is to satisfy the FDA as to the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit biological activity test (BAT). We have completed a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT and are finalizing our data submission. We believe that we remain on track to file a Complete Response for Surfaxin in the third quarter of 2011, which, after a six-month FDA review period, could lead to the potential approval of Surfaxin for the prevention of RDS in premature infants in the first quarter 2012.

We are developing Surfaxin LS and Aerosurf for the prevention and/or treatment of RDS in premature infants in both the United States and other major markets worldwide. Surfaxin LS is our initial lyophilized (freeze-dried) KL<sub>4</sub> surfactant that is resuspended to liquid form prior to use and is intended to improve ease of use for healthcare practitioners and potentially eliminate the need for cold-chain storage. Aerosurf is our initial aerosolized KL<sub>4</sub> surfactant that is administered through less-invasive means and is being developed to potentially obviate the need for endotracheal intubation and conventional mechanical ventilation. We believe that Aerosurf, if approved, will address a significant unmet medical need by providing practitioners with the alternative of administering surfactants to infants at risk for RDS through less invasive means, which may result in a potentially significant increase in the number of infants who will benefit from surfactant therapy.

Aerosurf combines our KL<sub>4</sub> surfactant with our aerosol delivery technologies: our proprietary capillary aerosolization device and our novel patient interface adapters. Our capillary aerosolization device has been initially designed to produce high quality, low-velocity aerosolized KL<sub>4</sub> surfactant for intra-pulmonary delivery for the prevention and/or treatment of RDS in premature infants. In developing our proprietary patient interface technology for Aerosurf, we focused on developing a patient interface and related componentry suitable for use with our capillary aerosolization technology in neonatal intensive care units (NICUs). We have also explored the potential utility of developing our patient interface technology to potentially benefit all patients receiving ventilatory support who require aerosolized medicines in a critical care setting. With research provided by an independent market research firm, we recently concluded a market assessment of our patient interface adapters and announced our intention to develop, and seek market authorization in the United States and the European Union for the series of our patient interface adapters under the trade name Afectair.

Afectair is a series of novel patient interface adapters and related componentry based on our proprietary patient interface technology that simplifies the effective delivery of any aerosolized medication to critical-care patients requiring ventilatory support by introducing aerosolized medications directly at the patient interface and minimizing the number of connections to the ventilatory circuitry. We are developing a regulatory plan to potentially gain marketing authorization for Afectair in the United States and the European Union and, if approved, believe that we could be in a position to initiate the commercial introduction of Afectair in both markets in 2012.



In addition to our lead products, as our resources permit, 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 conducted research and development activities with our KL<sub>4</sub> surfactant to potentially address acute lung injury (ALI) and cystic fibrosis and in the future may conduct further research and development activities to potentially address other diseases of the lung.

An important priority continues to be 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. We are engaged in discussions with potential strategic partners who potentially could provide development and commercial expertise as well as financial resources. We also intend to consider potential additional financings and other similar transactions to meet our capital requirements and continue to fund our operations. There can be no assurance, however, that we will successfully conclude any strategic alliance, financing or other similar transaction. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL<sub>4</sub> surfactant and aerosol drug delivery technologies and support our operations, we will continue to focus on our RDS programs, primarily Surfaxin, and Afectair, and conserve our resources, predominantly by curtailing and pacing investments in our other pipeline programs.

## **Business and Pipeline Programs Update**

The reader is referred to, and encouraged to read in its entirety “Item 1 – Business” in our Annual Report on Form 10-K for the year ended December 31, 2010 that we filed with the Securities and Exchange Commission (SEC) on March 31, 2011 (2010 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 pipeline programs since the filing of our 2010 Form 10-K and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, which we filed with the SEC on May 13, 2011:

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

We have completed a comprehensive preclinical program intended to satisfy the FDA’s requirements with respect to the BAT and are finalizing our data submission. We have manufactured a sufficient number of Surfaxin batches to generate the additional data requested by the FDA, and all related analytical and concordance has been completed. We believe that we remain on track to file the Complete Response in the third quarter of 2011, which, after an anticipated six-month FDA review cycle, could lead to potential U.S. marketing approval for Surfaxin in the first quarter of 2012. For a discussion of the history of our Surfaxin development program, *see*, in our 2010 Form 10-K, “Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – Surfaxin for the Prevention of RDS in Premature Infants.”

- **Surfaxin LS and Aerosurf Development Programs**

We have been conducting preclinical activities for both Surfaxin LS and Aerosurf to support our planned regulatory filings for these development programs. Among other things, we are continuing our efforts to complete the technology transfer of our Surfaxin LS lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in lyophilized formulations. We are currently seeking regulatory advice in the United States, and expect to engage in discussions with the FDA in the second half of 2011. We also plan later this year to seek regulatory guidance in Europe with respect to our development programs. To advance our Aerosurf program, we continue to work with third-party medical device experts to optimize the design of our capillary aerosolization device. Depending upon the progress of our device design optimization activities, we plan later this year to seek regulatory guidance for Aerosurf in the United States and potentially in Europe. We intend to initiate our clinical programs for each of these product candidates after we have developed a final regulatory strategy and after we have secured the necessary strategic alliances and/or capital. For a more detailed discussion of these development programs, *see*, in our 2010 Form 10-K, “Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – Surfaxin LS™ – Lyophilized Surfaxin for RDS in Premature Infants,” and “– Aerosurf for RDS in Premature Infants.”

- Afectair – A New Pipeline Program.

An important component of the Aerosurf program is our proprietary patient interface technology that simplifies the delivery of aerosolized medications to critical-care patients requiring ventilatory support. We have been developing this technology for use with our capillary aerosolization device to address RDS in premature infants. We have also recognized that this technology has potential application beyond our KL<sub>4</sub> surfactant and potentially could benefit any patient receiving ventilatory support (intermittent mechanical ventilation or continuous positive airway pressure (CPAP)) requiring aerosolized medications in a critical care setting. Based on an assessment that we conducted with the assistance of an independent market research firm, we have recently announced our intention to seek regulatory authorization to market Afectair in the United States and the European Union under the trade name Afectair™.

Afectair is initially a series of disposable novel patient interface adapters and related componentry that introduce aerosolized medications directly to the patient interface and minimizes the number of connections in the regulatory circuit without compromising ventilatory support. Afectair has the following characteristics:

- The initial product will be designed for use with jet nebulizer aerosol generators,
- A subsequent product, Afectair™ Duo, will be designed for use with vibrating mesh nebulizers (VMN), metered dose inhalers (MDI) and other aerosol generator technologies, including our capillary aerosol generator, and
- Each product will be available in two sizes, one for infants and another one for pediatric and adult patients.

We currently plan to file an application to clear Afectair with the FDA using a Class I exempt medical device registration process. Prior to marketing a Class I exempt medical device, the manufacturer must register its establishment, list the generic category or classification name of the medical device being marketed and pay a registration fee. If for any reason, the FDA determines that Afectair is a Class II medical device, we would seek to obtain FDA market authorization through the 510(k) clearance process, which would require us to demonstrate that Afectair is substantially equivalent to a legally marketed medical device and submit data that supports our equivalence claim. A third method for gaining approval to market a medical device is known as pre-marketing authorization (PMA), which would require us to independently demonstrate that Afectair is safe and effective. We do not believe that we will be required to file a PMA (or its equivalent in the European Union).

The European Union has comparable regulations to the FDA for the registration and marketing authorization of medical devices. We believe that, Afectair will be classified as a Class IIa device in the European Union, which will require us to obtain a “CE mark” by filing a statement of registration. We must first seek a review of a “Notified Body” that will conduct an audit to ensure that we and our manufacturers are in compliance with applicable quality regulations, and, if the audit is successful, will certify the product for a CE mark. We are working with a regulatory services firm to obtain the CE mark.

We believe that we potentially could gain marketing authorization (i) for the initial Afectair product, in the first half of 2012 in the U.S. and later in 2012 in the European Union; and (ii) for Afectair Duo, in late 2012 in the U.S. and in first half of 2013 in the European Union. If successful, we believe that the Afectair series of products has the potential to become a part of the standard of care for use in delivering aerosolized medicines to patients receiving ventilatory support in a critical care setting. We also believe that, after an up-take period following the introduction of Afectair, if marketing authorization is granted, revenues in the United States and the five largest countries in the European Union could potentially be between \$50 million and \$75 million in the fourth full year of sales, which could occur as early as 2016.

For a discussion of Afectair, including our business and regulatory strategy, estimated capital requirements and estimated market opportunity, if marketing authorization is granted for Afectair, and certain related risk factors, see, our Current Report on Form 8-K that we filed with the SEC on July 29, 2011, and “Risk Factors” in this Quarterly Report on Form 10-Q.

**CRITICAL ACCOUNTING POLICIES**

There have been no changes to our critical accounting policies since December 31, 2010. For more information on critical accounting policies, see, in our 2010 Form 10-K, “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies.” Readers are encouraged to review these disclosures in conjunction with their review of this Quarterly Report on Form 10-Q.

**RESULTS OF OPERATIONS**

The net loss for the three and six months ended June 30, 2011 was \$8.1 million (or \$0.34 per share) and \$11.9 million (or \$0.56 per share), respectively. The net loss for the three and six months ended June 30, 2010 was \$0.8 million (or \$0.07 per share) and \$6.9 million (or \$0.69 per share), respectively. Included in the net loss is the change in fair value of certain common stock warrants that are classified as derivative liabilities, resulting in non-cash expense of \$1.7 million and non-cash income of \$0.5 million for the three and six months ended June 30, 2011, respectively, and non-cash income of \$5.5 million and \$6.7 million for the three and six months ended June 30, 2010, respectively.

The operating loss for the three and six months ended June 30, 2011 was \$6.4 million and \$12.4 million, respectively, compared to \$6.2 million and \$13.3 million, respectively, for the same periods last year. Excluding non-cash items related to depreciation and stock-based compensation, the operating loss for the three and six months ended June 30, 2011 was \$5.9 million and \$11.4 million, respectively, compared to \$5.5 million and \$11.8 million, respectively, for the same periods last year.

**Revenue**

For the three and six months ended June 30, 2011, we recognized revenue of \$0.2 million and \$0.6 million, respectively, for funds received and expended under a Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health to support the development of aerosolized KL<sub>4</sub> surfactant for RDS. There were no revenues for the three or six months ended June 30, 2010.

**Research and Development Expenses**

Our research and development expenses are charged to operations as incurred and we track such costs by category rather than by project. As many of our research and development activities form a foundation for the development of our KL<sub>4</sub> surfactant technology platform, they benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist primarily of expenses associated with (a) manufacturing development, (b) development operations, and (c) direct pre-clinical and clinical programs.

Research and development expenses for the three and six months ended June 30, 2011 and 2010 are as follows:

<i>( in thousands)</i>	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
<b>Research and Development Expenses:</b>	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Manufacturing development	\$ 2,873	\$ 2,208	\$ 5,493	\$ 4,646
Development operations	1,111	1,359	2,442	2,600
Direct preclinical and clinical programs	631	796	1,300	1,250
<b>Total Research &amp; Development Expenses</b>	<b>\$ 4,615</b>	<b>\$ 4,363</b>	<b>\$ 9,235</b>	<b>\$ 8,496</b>

Included in research and development expenses were non-cash charges associated with stock-based compensation and depreciation of \$0.4 million and \$0.7 million for the three and six months ended June 30, 2011 and \$0.4 million and \$0.9 million for the three and six months ended June 30, 2010, 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.

Manufacturing development costs increased \$0.7 million and \$0.8 million for three and six months ended June 30, 2011 compared to the same periods in 2010. The increases are primarily due to costs incurred related to the manufacture of Surfaxin batches to support our Complete Response, which we anticipate filing with the FDA in the third quarter of 2011.

#### Development Operations

Development operations includes: (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our research and development programs; (ii) medical affairs activities to provide scientific and medical education support in connection with our KL<sub>4</sub> surfactant and aerosol delivery technologies programs; (iii) design and development activities related to the development and manufacture of our novel capillary aerosolization systems, including an aerosol generating device and disposable dose delivery packets, and our novel patient interface adapters, for use in our preclinical programs, our anticipated clinical programs, and, if approved, commercial use and; (iv) pharmaceutical development activities, including development of a lyophilized 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.

Development operations expenses decreased \$0.2 million for both the three and six months ended June 30, 2011 compared to the same periods in 2010. The decreases are primarily due to a reduction in personnel related costs in conjunction with the Company's ongoing efforts to conserve financial resources since the receipt of the 2009 Complete Response Letter.

#### Direct Preclinical and Clinical Programs

Direct pre-clinical and clinical programs include: (i) activities related to addressing the items identified in the 2009 Complete Response Letter; (ii) pre-clinical activities, including preparatory activities for our anticipated clinical trials for Surfaxin LS and Aerosurf for RDS in premature infants, toxicology studies and other pre-clinical studies to obtain data to support potential Investigational New Drug (IND) and NDA filings for our product candidates; and (iii) 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), including, in 2010, activities related to the Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering with Acute Respiratory Failure (ARF).

The decrease of \$0.2 million in direct preclinical and clinical program expenses for the three months ended June 30, 2011, as compared to the same period in 2010, is primarily due to expenses incurred in 2010 associated with the completed Phase 2 ARF clinical trial.

Direct preclinical and clinical program expenses for the six months ended June 30, 2011 were comparable to the same period in 2010. An increase in costs associated with activities to address issues identified in the 2009 Complete Response Letter were offset by a decrease in costs associated with the completed Phase 2 ARF clinical trial.

In an effort to conserve our financial resources, we plan to continue limiting investments in clinical programs until we have secured the necessary strategic alliances and/or capital. At the same time, we are planning to seek regulatory guidance as needed in the United States and Europe to discuss the requirements for our regulatory packages, including potential trial design requirements, to prepare for initiation of our planned clinical trials when we have secured appropriate strategic capital.

### Research and Development Projects

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete individual projects in development are not reasonably estimable. With every phase of a development project, there are significant unknowns that may significantly impact cost projections and timelines. As a result of the number and nature of these factors, many of which are outside our control, the success, timing of completion and ultimate cost, of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. Certain of the risks and uncertainties affecting our ability to estimate projections and timelines are discussed in our 2010 Form 10-K, including in “Item 1 – Business – Government Regulation;” “Item 1A – Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Research and Development Expenses.”

Our lead development projects are initially focused on (i) the management of RDS in premature infants and include Surfaxin, Surfaxin LS and Aerosurf, and (ii) developing our proprietary patient interface technology to potentially commercialize Afectair, which will be directed to delivery of aerosolized medications to any patient on ventilatory support. These and our other product programs are described in “Overview – Business and KL<sub>4</sub> Pipeline Programs Update,” and, in our 2010 Form 10-K, “Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine,” and in our Current Report on Form 8-K that we filed with the SEC on July 29, 2011.

Since the filing of our 2010 Form 10-K, we have made the following changes in our plans for our other research and development programs:

- We have announced our intent to introduce our proprietary patient interface adapters as a stand-alone product under the trade name Afectair™.
  - To bring Afectair to the current stage of development, we have leveraged the research and development activities related to development of the patient interface adapter for Aerosurf. Thus, while the specific investments are not readily determinable, they have been fully expensed and reported in our financial statements to date.
  - We hold exclusive rights to Afectair. In March 2009, we filed an international patent application (PCT US/2009/037409), directed to improvements of an aerosol delivery system and ventilation circuit adaptor, in the United States, Europe and Japan, among other countries, and our application is currently pending. See, our 2010 Form 10-K, “– Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights,” and “– Proprietary Platform – Surfactant and Aerosol Technologies – Our Aerosolization Device Technology – Novel Patient Interfaces and Related Componentry.” The status of our patent will be “patent pending” until a patent is or is not issued, which we anticipate could be in late 2012, or later. We have conducted a series of reviews with patent experts and anticipate that a patent will issue; however, the various authorities have broad discretion in connection with the issuance of patents and there can be no assurance that a patent will issue within that time frame, if at all, in any or all of the jurisdictions in which we have filed applications.
  - To complete the work necessary to meet the regulatory requirements for potentially gaining marketing authorization for the initial Afectair product in the U.S. and the European Union, we anticipate an additional investment of between \$0.5 million and \$1 million. This amount primarily represents the cost of manufacturing sample devices for review by the Notified Body order to obtain marketing authorization for Afectair in the European Union.
  - If marketing authorization is granted, we believe that preparing for the commercial launch will involve a further investment of approximately \$1 million, primarily to initiate development of an in-house medical affairs and marketing management capability. This investment will be made only after marketing authorization is granted. We anticipate that, if Surfaxin is approved, we will also use these medical affairs personnel to provide medical education support for Surfaxin, as both products will be of interest to many of the same medical practitioners and involve many of the same medical congresses, many of the same journals for publication and many of the same hospitals, providing certain economies for both of these products.

- o In 2012, we anticipate an additional investment of between \$0.5 million and \$1 million for the Afectair Duo product to potentially gain marketing authorization, and initiate manufacturing activities.
- We continue to make progress in our KL<sub>4</sub> surfactant pipeline programs. For a discussion of these programs and the introduction of Afectair as a stand-alone product, see, in this MD&A – “Overview – Business and Pipeline Programs Update.” At the present time, we continue to focus primarily on Surfaxin and Afectair and are conserving our resources, predominantly by curtailing and pacing investments in our other pipeline programs.

### **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 June 30, 2011 and 2010 were \$2.0 million and \$1.9 million, respectively. Included in general and administrative expenses were non-cash charges associated with stock-based compensation and depreciation of \$0.1 million and \$0.3 million, respectively. Excluding the charges associated with stock-based compensation and depreciation, general and administrative expenses increased \$0.3 million primarily due to employee cash incentive payments and investments related to Afectair.

General and administrative expenses for the six months ended June 30, 2011 and 2010 were \$3.8 million and \$4.8 million, respectively. Included in general and administrative expenses were non-cash charges associated with stock-based compensation and depreciation of \$0.3 million and \$0.6 million, respectively. Additionally, general and administrative expenses for the six months ended June 30, 2010 included a one-time charge of \$1.0 million associated with certain contractual cash severance payments made to our former President and Chief Executive Officer. See, in our 2010 Form 10-K, “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Contractual Commitments – Former CEO Commitment.” Excluding the one-time severance obligation and charges associated with stock-based compensation and depreciation, general and administrative expenses increased \$0.4 million. The increase is primarily due to employee cash incentive payments and investments related to Afectair.

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

We account for common stock warrants in accordance with applicable accounting guidance provided in Accounting Standards Codification (ASC) Topic 815 – “Derivatives and Hedging — Contracts in Entity’s Own Equity,” as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. The registered warrants that we issued in May 2009 and February 2010 warrants were classified as derivative liabilities and valued using the Black-Scholes pricing model. The five-year registered warrants that we issued in February 2011 (February 2011 five-year warrants) were classified as derivative liabilities and valued using a trinomial pricing model. Valuations of these warrants occur 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.” See, Note 6 to our Consolidated Financial Statements in this Quarterly Report on Form 10-Q.

The change in the fair value of common stock warrant liability for the three months ended June 30, 2011 and 2010 resulted in expense of \$1.7 million and income of \$5.5 million, respectively, due primarily to changes in our common stock share price during the periods.

The change in the fair value of common stock warrant liability for the six months ended June 30, 2011 and 2010 resulted in income of \$0.5 million and \$6.7 million, respectively, due primarily to a decrease in our common stock share price during the periods.

**Other Income and (Expense)**

Other income and (expense) for the three and six months ended June 30, 2011 and 2010 is as follows:

<i>(Dollars in thousands)</i>	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Interest income	\$ 4	\$ 3	\$ 7	\$ 6
Interest expense	(6)	(89)	(11)	(331)
Other income / (expense)	(1)	2	(5)	18
Other income / (expense), net	<u>\$ (3)</u>	<u>\$ (84)</u>	<u>\$ (9)</u>	<u>\$ (307)</u>

Interest income consists of interest earned on our cash and cash equivalents. To ensure preservation of capital, we invest our cash in an interest bearing operating cash account and a treasury-based money market fund.

Interest expense for the three and six months ended June 30, 2011 consists of interest on our equipment financing facilities.

Interest expense for the three and six months ended June 30, 2010 consists of (i) interest accrued on the outstanding balance of our loan then outstanding with PharmaBio Development, Inc. (PharmaBio), the former strategic investment subsidiary of Quintiles Transnational Corp., (ii) interest on our equipment financing facilities and (iii) amortization of deferred financing costs for the warrant issued to PharmaBio in October 2006 as consideration for a restructuring of our loan.

The decrease in our interest expense for the three and six months ended June 30, 2011 as compared to the same periods in 2010 is due to the payment in full in 2010 of the principal amount outstanding under our loan with PharmaBio, full amortization of deferred financing costs associated with the warrant that we issued to PharmaBio in October 2006, and 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 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 in premature infants and Afectair, if approved.

Our future capital requirements depend upon many factors, including (i) the success of our efforts to file the Complete Response for Surfaxin and potentially to gain regulatory approvals for Surfaxin in the United States and for Afectair in the United States and Europe, (ii) 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, and (iii) the success of our efforts to raise capital through financings and other transactions. We believe that anticipated revenue from the commercial introduction of Surfaxin and/or Afectair, if approved, could serve as a potential non-dilutive source of funds to support our research and development activities in the future. We also believe that our ability to successfully enter into meaningful strategic alliances will likely improve if we are able to gain regulatory approvals for Surfaxin and advance our Surfaxin LS and Aerosurf programs towards initiation of clinical trials. In addition to seeking strategic alternatives, including without limitation potential business alliances, commercial and development partnerships, and other similar opportunities, we continue to consider potential additional financings and other similar transactions to meet our capital requirements and continue to fund our operations. Even if we succeed in gaining regulatory approvals for, and subsequently commercializing, Surfaxin and Afectair and our other product candidates; in securing strategic alliances; and in raising additional capital to support our research and development activities as needed, we may never achieve sufficient sales revenue to achieve or maintain profitability.

There can be no assurance that that products we develop, including Surfaxin and Afectair, will obtain necessary regulatory approvals, that any approved product will be commercially viable, that we will be able to secure strategic partners or collaborators to support and provide expert advice to guide our activities, that our research and development activities will be successful, that any CEFF or other facility will be available for future financings, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL<sub>4</sub> surfactant and aerosol drug delivery technologies and fund our operations, we will continue to limit investment in our pipeline programs. In 2011, we plan to continue to manage our expenditures and focus our financial resources on our RDS programs, primarily in support of the potential approval of Surfaxin and Afectair.

We believe that we have sufficient cash to fund our planned research and development activities and operations through the first quarter of 2012. Our plans include the filing of the Complete Response and potential approval of Surfaxin, which we anticipate could occur in the first quarter 2012, regulatory filings and the potential commercial introduction of Afectair, which we believe may occur in 2012, and limited regulatory activities to potentially advance Surfaxin LS and Aerosurf towards planned Phase 3 and Phase 2 clinical trials.

As of June 30, 2011, we had cash and cash equivalents of \$21.5 million. We also have a CEFF, which could allow us, at our discretion, to raise capital (subject to certain conditions, including minimum stock price and volume limitations) at a time and in amounts deemed suitable for us to support our business plans. Based on the closing market price of our common stock on August 5, 2011 (\$2.20) and assuming that all available shares are issued, the potential availability under our CEFF is approximately \$2.6 million. See, Note 4 – “Stockholders’ Equity – Committed Equity Financing Facility (CEFF),” and, in our 2010 Form 10-K, “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs).” In addition, in connection with our February 2011 public offering, we issued 15-month warrants to purchase our five million shares of our common stock at an exercise price of \$2.94 (15-month warrants). If the market price of our common stock should exceed \$2.94 at any time prior to May 2012 (the expiration date of the 15-month warrants), we potentially could raise up to an additional \$14.7 million in proceeds if the holders determine (in their discretion) to exercise the 15-month warrants and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants. There can be no assurance, however, that the market price of our stock will be above \$2.94 in that timeframe, if ever, that we will have in place at that time an effective registration statement, or that any holders of the warrants will choose to exercise them for cash prior to the expiration date.

As of June 30, 2011, of the 50 million shares of common stock authorized under our Certificate of Incorporation, we had available for issuance, and not otherwise reserved for future issuance, approximately 10.1 million shares of common stock. To assure that we have sufficient authorized shares of common stock to effectively execute our business strategies, our Board of Directors has approved, subject to stockholder approval at our Annual Meeting of Stockholders to be held on October 3, 2011, an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 50 million to 100 million. If our stockholders do not approve the amendment, we may be unable to enter into favorable transactions that require the issuance of common stock, which could include strategic alliances and collaboration arrangements, or undertake additional financings, without first seeking stockholder approval, a process that would require a special meeting of stockholders, is time-consuming and expensive and could impair our ability to efficiently raise capital when needed, if at all. If the amendment is not approved, we may not have access to a sufficient number of authorized shares of common stock and may be forced to further limit development of many, if not all, of our drug product candidates and further cut back on our activities to conserve our cash resources. If for any reason, we do not have a sufficient number of authorized shares to enable us to secure required capital, we may be forced to curtail all of our activities and, ultimately, potentially could be forced to cease operations.



## Cash Flows

As of June 30, 2011, we had cash and cash equivalents of \$21.5 million compared to \$10.2 million as of December 31, 2010. Cash outflows before financings for the six months ended June 30, 2011 consisted of \$11.1 million used for ongoing operating activities and \$0.1 million used for debt service. During the first six months of 2011, we raised aggregate gross proceeds of \$24.5 million, including \$23.5 million (\$21.6 million net) from a public offering in February 2011 and \$1.0 million from a January 2011 financing under our CEFF.

### Cash Flows From Operating Activities

Net cash used in operating activities was \$11.1 million and \$13.7 million for the six months ended June 30, 2011 and 2010, respectively.

Net cash used in operating activities is a result of our net losses adjusted for non-cash items associated with the fair value adjustment of common stock warrants (income of \$0.5 million and \$6.7 million in 2011 and 2010, respectively), stock-based compensation and depreciation expense (\$1.2 million and \$1.8 million in 2011 and 2010, respectively), and changes in working capital. Cash flows used in operating activities for the six months ended June 30, 2010 included a one-time payment of \$1.1 million to satisfy our severance obligations to our former President and Chief Executive Officer.

### Cash Flows From Investing Activities

Net cash used in investing activities represents purchases of equipment of \$26,000 and \$73,000 for the six months ended June 30, 2011 and 2010, respectively.

### Cash Flows From Financing Activities

Net cash provided by financing activities was \$22.5 million and \$21.4 million for the six months ended June 30, 2011 and 2010, respectively.

Cash provided by financing activities for the six months ended June 30, 2011 included net proceeds of \$21.6 million from the February 2011 public offering and \$1.0 million from a January 2011 financing under our CEFF. See, “-Common Stock Offerings – Financings under the 2008 Shelf Registration Statement.” Cash used in financing activities for that period reflect principal payments on our equipment loan and capital lease obligations of \$0.1 million.

Net cash provided by financing activities for the six months ended June 30, 2010 included net proceeds of \$15.1 million from the February 2010 public offering, \$9.1 million from the June 2010 public offering and \$2.1 million from our securities purchase agreement with PharmaBio, partially offset by principal payments under our PharmaBio loan agreement of \$4.5 million and on our equipment loan and capital lease obligations of \$0.4 million.

## Committed Equity Financing Facility (CEFF)

As of June 30, 2011, we had one Committed Equity Financing Facility dated June 11, 2010 (CEFF) with Kingsbridge Capital Limited (Kingsbridge). Under the CEFF, Kingsbridge is committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFF allows us at our discretion to raise capital for a period of three years ending June 11, 2013, at the time and in amounts deemed suitable to us. Two prior CEFFs, dated May 22, 2008 and December 12, 2008, expired in June 2011 and February 2011, respectively. We are not obligated to utilize any of the funds available under the CEFF. Our ability to access funds available under the CEFF is subject to certain conditions, including stock price and volume limitations. See, in our 2010 Form 10-K, “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs)” for a detailed description of our CEFF.

As of June 30, 2011, there were approximately 1.3 million shares potentially available for issuance (up to a maximum of \$32.6 million) under the CEFF, provided that the volume-weighted average price per share of our common stock (VWAP) on each trading day must be at least equal to a price that we designate in the draw down notice, which may be either a price that we specify, but not less than \$0.20 per share, or 90% of the closing market price on the trading day preceding the first day of the draw down. Based on the closing market price of our common stock on August 5, 2011 (\$2.20) and assuming that all available shares are issued, the potential availability under our CEFF is approximately \$2.6 million.

Use of the CEFF is subject to certain other covenants and conditions, including aggregate share and dollar limitations for each draw down. See, in our 2010 Form 10-K, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facilities (CEFFs)" for a detailed description of our CEFF.

We anticipate using the CEFF to support our working capital needs and maintain cash availability in 2011.

In January 2011 we completed a financing under our the CEFF, resulting in gross proceeds of \$1.0 million from the issuance of 314,179 shares of our common stock at an average price per share, after applicable fees and discounts, of \$3.16.

### **Common Stock Offerings**

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of common stock offerings. A shelf registration that we filed on Form S-3 (No. 333-151654) in June 2008 (2008 Shelf Registration Statement) recently expired. On June 8, 2011 we filed a universal shelf registration statement on Form S-3 (No. 333-174786) that was declared effective on June 21, 2011 (2011 Shelf Registration Statement) with respect to the offering from time to time of up to \$200 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.

As of June 30, 2011, \$200 million remained unissued under the 2011 Shelf Registration Statement. If the aggregate market value of our common stock held by non-affiliates (public float) remains below \$75 million, the number of shares that we may offer and sell pursuant to the 2011 Shelf Registration Statement and any new universal shelf registration statements within any 12 calendar month period beginning as of March 31, 2011 may be limited to an amount equal to one-third of the public float at the time of the transaction.

#### *Financings under the 2008 Shelf Registration Statement*

On February 22, 2011, we completed a registered public offering of 10 million shares of our common stock, 15-month warrants to purchase five million shares of our common stock, and five-year warrants to purchase five million shares of our common stock. The securities were sold as units, with each unit consisting of one share of common stock, a fifteen-month warrant to purchase one half share of common stock, and a five-year warrant to purchase one half share of common stock, at a public offering price of \$2.35 per unit, resulting in gross proceeds to us of \$23.5 million (\$21.6 million net). The 15-month warrants expire in May 2012 and are exercisable at a price per share of \$2.94. The five-year warrants expire in February 2016 and are exercisable at a price per share of \$3.20. The warrants are exercisable for cash only, except that if the related registration statement or an exemption from registration is not otherwise available for the resale of the warrant shares, the holder may exercise on a cashless basis. The exercise price and number of shares or type of property issuable upon exercise of the warrants are subject to customary adjustments in the event of corporate events (as described in the warrants). In addition, the exercise price of the five-year warrants is subject to adjustment if we issue or sell common stock or securities convertible into common stock (in each case, subject to certain exceptions) at a price (determined as set forth in the warrant) that is less than the exercise price of the warrant.

### **Debt**

Historically, we have funded, 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.

In April 2010, we restructured our \$10.6 million loan with PharmaBio and agreed to (a) an immediate payment in cash of \$6.6 million (\$4.5 million in principal and \$2.1 million in accrued interest) and (b) payment of the remaining \$4 million principal amount in \$2 million installments on each of July 30 and September 30, 2010. In addition, PharmaBio surrendered to us for cancellation warrants to purchase an aggregate of 159,574 shares of our common stock. See, in our 2010 Form 10-K, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Loan with PharmaBio Development Inc." As of December 31, 2010, all of our obligations related to the loan with PharmaBio were paid in full.

Equipment Financing Facilities

As of June 30, 2011, approximately \$14,000 was outstanding under a May 2007 Credit and Security Agreement with GE Business Financial Services Inc. (formerly Merrill Lynch Business Financial Services Inc). The right to draw under this facility expired in 2008 and the remaining outstanding balance will be paid in full in October 2011.

As of June 30, 2011, approximately \$0.3 million was outstanding (\$64,000 classified as current liabilities and \$260,000 as long-term liabilities) under 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 \$0.5 million loan to us in 2008 from the Machinery and Equipment Loan Fund.

See, in our 2010 Form 10-K, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Equipment Financing Facilities."

**ITEM 4. CONTROLS AND PROCEDURES**

Evaluation of disclosure controls and procedures

Our management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. 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, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our Chief Executive Officer and our Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in internal controls

There were no changes in 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 June 30, 2011 that have materially affected, or are 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**

***Afectair™ will require FDA and international regulatory marketing authorization which may be costly and may not occur.***

Afectair is not registered with or approved by the FDA and may require regulatory pre-marketing approval in the United States before commercialization can commence. Whether or not regulatory pre-marketing approval is required is based on whether or not Afectair is classified as a Class I exempt medical device. Although we currently believe that Afectair qualifies as a Class I exempt medical device, which means that Afectair may be cleared by the FDA without pre-marketing approval, there can be no assurance that it will be subject to registration and listing only. If a specific marketing approval is required, the regulatory process can be a costly, time consuming, lengthy and uncertain process and no assurances can be given as to the classification, timing or expenses involved not whether any Afectair product ultimately will receive the required regulatory marketing authorizations.

In order to market products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory marketing authorizations and comply with numerous and varying regulatory requirements. We may not obtain foreign regulatory marketing authorizations on a timely basis, if at all. Marketing authorization by the FDA would not ensure marketing authorization by regulatory agencies in foreign countries. A failure or delay in obtaining marketing authorization in one jurisdiction may have a negative effect on the marketing authorization process in other jurisdictions, including the FDA. The failure to obtain regulatory marketing authorization in domestic or foreign jurisdictions could harm our business.

Delays in gaining regulatory marketing authorization can be extremely costly in terms of lost sales and marketing opportunities, as well as increased regulatory costs. Moreover, even if the regulatory marketing authorization of Afectair is achieved, the marketing authorization will be limited to specific indications or uses or limited with respect to its distribution. Expanded or additional indications for an approved device may not be approved, which could limit our potential revenues. Foreign regulatory authorities may apply different or similar limitations or may refuse to grant any marketing authorization. Consequently, even if we believe that our submissions are sufficient to support regulatory marketing authorization for Afectair, the FDA and foreign regulatory authorities may not ultimately grant marketing authorization for commercial sale in any jurisdiction. If Afectair is not approved, our ability to generate revenues will be limited and our business will be adversely affected.

***Afectair may be subject to varied and rigorous FDA regulatory pathways and procedures.***

Our goal is to have Afectair regulated by the FDA as a Class I exempt medical device. A Class I classification is designed for low risk devices in which sufficient information exists to establish general and specific controls that provide reasonable assurance of safety and effectiveness. If Afectair is classified as a Class I exempt medical device, to obtain marketing authorization, the manufacturer must register its establishment, list the generic category or classification name of the medical device being marketed and pay a registration fee through a registration and listing process. If Afectair is classified as a non-exempt Class I or a Class II medical device, marketing authorization is obtained through a 510(k) clearance process. In a 510(k) application, applicants must demonstrate that the proposed device is substantially equivalent to an existing approved product, or “predicate device.” If a product employs new or novel technology such that no predicate device exists, the FDA will automatically classify the device as a Class III device under regulatory statute. The applicant may then request that a risk-based classification determination be made for the device under Section 513(f)(2) of the U.S. Food, Drug and Cosmetic Act. This process is also known as a “de novo” or “risk based” classification.

If the FDA determines that a predicate device does not exist for Afectair, we may be required to submit a request for Pre-Market Approval under the de novo protocol as required by the Section 513(f)(2) guidance document and be subject to significant regulatory delays. In addition, recent, widely-publicized events concerning the safety of certain drug, food and medical device products have raised concerns among members of Congress, medical professionals, and the public regarding the FDA’s handling of these events and its perceived lack of oversight over regulated products. The increased attention to safety and oversight issues could result in a more cautious approach by the FDA to marketing authorizations for devices such as Afectair.

There is no guarantee that the FDA will permit registration of Afectair as a Class I exempt medical device or grant market authorization or designate Afectair as a Class II device in a timely manner, if at all. Even if FDA market authorization is received, we may encounter significant delays in receiving such authorization. If unexpected delays occur, it could have a material adverse effect on our business.

***Marketing authorization to promote, manufacture and/or sell Afectair, if granted, will be limited and subject to continuing review.***

Even if regulatory market authorization of a product is granted, such authorization may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing authorization has not been obtained. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to serious regulatory enforcement actions, including some of those listed above. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Due to these legal constraints, our distributors’ sales and marketing efforts will focus only on the general technical attributes and benefits of Afectair and the FDA cleared indications for use.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of Afectair, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with Afectair, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market or regulatory enforcement actions.

***Product inadequacies could lead to recalls and harm our reputation, business and financial results.***

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining marketing authorization, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory authorization. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

In addition, if approved for sale, we could be exposed to the risk of device failures and malfunctions, which might result in a recall of the product. Recalls of the product can occur at any time and can impact our business operations. Recalls can be both time consuming and costly. Recalls might also impact future sales through negative market perception, or might result in legal action against us by those affected by the recall or the regulatory authorities whose role it is to supervise the product.

Even if FDA marketing authorization is ultimately received for Afectair, which cannot be assured, the occurrence of subsequent, unforeseen medical complications or subsequent instances of noncompliance with FDA or other regulatory requirements could lead to enforcement action against us. Enforcement action may result in, among other things, withdrawal of marketing authorization, injunctions, suspension of production, recall or seizure of products, and fines or criminal prosecution, any and all of which could have a material adverse effect on our business and financial condition.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a mandatory recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, initiate a field correction or removal, known as a recall, for a product if any material deficiency in a device is found. A government mandated or voluntary recall by us or our third-party manufacturers or suppliers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. We are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Under the FDA medical device reporting regulation, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

***Product liability claims could hurt our reputation and finances.***

Product liability claims could have a material adverse effect on our business. Our business may be exposed to an inherent risk of potential product liability claims relating to the development, manufacturing, testing, marketing and sale of the Afectair medical device. No assurance can be given that we will be able to secure, maintain or increase our product liability insurance on favorable terms, if at all, and such insurance might not provide adequate coverage against potential liabilities. A successful claim brought against us in excess or outside of our insurance coverage could not only have an adverse effect on our financial position, but could also hinder our ability to gain endorsement of the product by healthcare professionals.

***The cost of materials required for the manufacture of Afectair may increase or be higher than anticipated.***

The components of Afectair are manufactured from high-quality medical grade materials that are generally recognized as safe. Suppliers of these materials, due to a change in their pricing policies or an increase in raw materials costs, might charge us increasingly higher than anticipated prices. In turn, we might experience diminishing profit margins or remain unprofitable indefinitely.

***Our future results could differ significantly from the financial estimates included in this Current Report.***

Our estimates of market size and business opportunities included in this Quarterly Report on Form 10-Q are based in part on our analysis of data derived from the following sources, among others: CDC National Vital Statistics, 2005: Births by birth weight (CDC Website) Annual Summary of Vital Statistics: 2006; Pediatrics, Martin et al. Vermont Oxford Network (VON) data; 2005, 2006; HCUP Hospital Discharge data, 2008; Hospital Insurance Claim Database, 2009; Market Intelligence Report on Number of ICU Beds in EU5 Countries; Primary Market Research, December 2010 and May 2011. In addition, our analysis and assumptions take into account estimated patient populations, expected adoption rates of Afectair, current pricing, economics and anticipated potential pharmaco-economic benefits of our drug and medical device products, if approved. We provide estimates and projections to give the reader an understanding of our strategic priorities, but we caution that the reader should not rely on our estimates and projections. These estimates and projections are forward-looking statements, which we intend be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Further, although we believe that the assumptions underlying these estimates and projections are reasonable, there can be no assurance that such assumptions will prove to be correct. Actual results will vary from the projected results, and such variations may be material and adverse. We also reserve the right to conduct business in a manner different from that set forth in the assumptions as changing circumstances require.

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

During the three months ended June 30, 2011, we did not issue any unregistered shares of common stock. We did not repurchase any shares of our common stock during the quarter ended June 30, 2011.

**ITEM 6. EXHIBITS**

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

**SIGNATURES**

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

**Discovery Laboratories, Inc.  
(Registrant)**

Date: August 15, 2011

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

Date: August 15, 2011

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), as amended as of December 28, 2010	Incorporated by reference to Exhibit 3.1 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as filed with the SEC on June 30, 2011.
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	Class C Investor Warrant, dated April 17, 2006, issued to Kingsbridge Capital Limited (Kingsbridge)	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.
4.3	Warrant Agreement, dated November 22, 2006	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on November 22, 2006.
4.4	Warrant Agreement dated May 22, 2008 by and between Kingsbridge and Discovery	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on May 28, 2008.
4.5	Warrant Agreement dated December 12, 2008 by and between Kingsbridge 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.
4.6	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.
4.7	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.
4.8	Warrant Agreement, dated as of April 30, 2010, by and between Discovery and 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 April 28, 2010.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
4.9	Warrant Agreement dated June 11, 2010 by and between Kingsbridge and Discovery	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2010.
4.10	Form of Five-Year Warrant issued on June 22, 2010	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 17, 2010.
4.11	Form of Short-Term Warrant issued on June 22, 2010	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 17, 2010.
4.12	Warrant Agreement, dated as of October 12, 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 October 13, 2010.
4.13.	Form of Voting Agreement between RSA Holders and Discovery dated November 12, 2010	Incorporated by reference to Exhibit 4.13 to Discovery's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as filed with the SEC on June 30, 2011.
4.14	Form of Five-Year Warrant issued on February 22, 2011	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 16, 2011.
4.15	Form of Short-Term Warrant issued on February 22, 2011	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 16, 2011.
10.1	Separation of Employment Agreement and General Release Agreement dated as of July 12, 2011, between Discovery and David L. Lopez, Esq., C.P.A.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 12, 2011.
<a href="#">10.2</a>	Amendment dated August 11, 2011 to the Employment Agreement dated October 12, 2010 between Discovery and W. Thomas Amick, Chairman of the Board and Chief Executive Officer	Filed herewith.
<a href="#">31.1</a>	Certification of Chief Executive Officer (principal executive officer) pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
<a href="#">31.2</a>	Certification of Chief Financial Officer (principal financial officer) pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.

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<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
<a href="#">32.1</a>	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith.
101	Financial Statements from the Quarterly Report on Form 10-Q of Discovery for the quarter ended June 30, 2011, filed on August 10, 2011, formatted in XBRL: (i) Consolidated Balance Sheet, (ii) Consolidated Statement of Operations, (iii) Consolidated Statement of Cash Flows, and (iv) Notes to Consolidated Financial Statements.	Filed herewith

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August 11, 2011

W. Thomas Amick  
c/o Discovery Laboratories, Inc.  
2600 Kelly Road  
Suite 100  
Warrington, PA 18976

Re: Amendment to Employment Agreement

Dear Mr. Amick,

This amendment is attached to and made part of the Employment Agreement dated as of October 12, 2010 between you and Discovery Laboratories, Inc. (the "Agreement") and is effective as of July 18, 2011. The Agreement is hereby amended as set forth below. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Agreement.

1. Section 2 of the Agreement is hereby amended to provide (i) that the Term of the Agreement shall continue through May 3, 2010, and (ii) that, commencing on May 4, 2010, and on each May 4<sup>th</sup> thereafter, the Term of the Agreement shall automatically be extended for one additional year, except in the event of notice as provided for therein."

2. In addition to the benefits provided in Section 5(e) (Reimbursement of Business Expenses), the Company shall reimburse you for expenses associated with travel, local housing and other incidentals, in accordance with guidelines of the Internal Revenue Service, in amounts not to exceed \$55,025 during the period from January 1, 2011 through May 3, 2012. In addition, any amounts payable hereunder shall be subject to tax gross-up payments.

Except as amended herein, the remaining terms and conditions of the Agreement shall remain in full force and effect. This addendum confirms an agreement between you and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and mutual promises made in connection therewith. Please indicate your acceptance of the terms contained herein by signing both copies of this amendment, retaining one copy for your records, and forwarding the remaining copy to the Company.

DISCOVERY LABORATORIES, INC.

By: /s/ John G. Cooper  
Name: John G. Cooper  
Title: President and Chief Financial Officer

By: /s/ W. Thomas Amick  
Name: W. Thomas Amick



## CERTIFICATIONS

I, W. Thomas Amick, certify that:

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

Date: August 15, 2011

/s/ W. Thomas Amick

W. Thomas Amick

Chairman of the Board and Chief Executive Officer

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## CERTIFICATIONS

I, John G. Cooper, certify that:

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

Date: August 15, 2011

/s/ John G. Cooper

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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 Quarterly Report on Form 10-Q for the period ended June 30, 2011 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 15, 2011

/s/ W. Thomas Amick

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

/s/ John G. Cooper

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.

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