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

FORM 10-Q

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

For the quarterly period ended September 30, 2011

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3171943**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

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

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 x NO o

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

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

As of November 8, 2011, 24,499,497 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

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PART I - FINANCIAL INFORMATION

PART II - OTHER INFORMATION

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, including Surfaxin® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants; plans regarding our efforts to register our novel ventilator circuit / patient interface connectors for marketing in the United States and European Union; the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our KL_4 surfactant technology and 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; 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:

- the risk that, if 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);
- the risk that, if we are unable for any reason to obtain approval for Surfaxin® in the United States, or if approval of Surfaxin is delayed for a significant period of time, or if we are unable to introduce Afectair™ in the United States and European Union markets as planned, we may have difficulty securing additional capital, which could have a material adverse effect on our ability to continue our research and development programs and operations.
- 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;
- risks related to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug product and medical device candidates, including (i) our lead drug products that we are developing to address respiratory distress syndrome (RDS) in premature infants: Surfaxin for the prevention of RDS, Surfaxin LS™ (our initial lyophilized (freeze-dried) formulation of Surfaxin, and Aerosurf® (our initial aerosolized KL_4 surfactant based on our capillary aerosolization technology and novel ventilator circuit / patient interface connector); and (ii) Afectair™, a series of novel ventilator circuit / patient interface connectors, which we plan to introduce as a stand-alone products in 2012;

- the risk that we and the 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 recently-completed comprehensive preclinical program, which was intended 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 distinguish 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;
- 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) or other regulatory bodies may not permit the registration of Afectair, if at all, within the anticipated time frame;
- 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, if we succeed in gaining marketing authorization for 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 marketing authorization for 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_4 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, ventilator circuit / patient interface connectors 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, 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 that the unfavorable credit and economic 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), and that additional equity financings could result in substantial equity dilution or result in an adjustment to the exercise price of the five-year warrants we issued in February 2011 (which contain price-based anti-dilution revisions);

- risks related to our need for significant additional capital to execute the commercial introduction of our products, if approved, 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)

	September 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 15,411	$ 10,211
Prepaid expenses and other current assets	327	285
Total Current Assets	15,738	10,496
Property and equipment, net	2,585	3,467
Restricted cash	400	400
Other assets	-	174
Total Assets	$ 18,723	$ 14,537
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,386	$ 1,685
Accrued expenses	3,003	3,286
Common stock warrant liability	8,599	2,469
Equipment loans and capitalized leases, current portion	74	136
Total Current Liabilities	13,062	7,576
Equipment loans and capitalized leases, non-current portion	242	301
Other liabilities	691	634
Total Liabilities	13,995	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; 24,320 and 13,822 shares issued, 24,299 and 13,801 shares outstanding respectively, at September 30, 2011 and December 31, 2010	24	14
Additional paid-in capital	400,877	385,521
Accumulated deficit	(393,119)	(376,455)
Treasury stock (at cost); 21 shares at September 30, 2011 and December 31, 2010	(3,054)	(3,054)
Total Stockholders' Equity	4,728	6,026
Total Liabilities & Stockholders' Equity	$ 18,723	$ 14,537

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

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenue	$ –	$ –	$ 582	$ –
Expenses:				
Research and development	3,981	4,727	13,216	13,223
General and administrative	2,189	1,476	5,975	6,273
Total expenses	6,170	6,203	19,191	19,496
Operating loss	(6,170)	(6,203)	(18,609)	(19,496)
Change in fair value of common stock warrant liability	1,422	(365)	1,957	6,384
Other income / (expense):				
Interest and other income	3	3	10	27
Interest and other expense	(6)	(19)	(22)	(350)
Other income / (expense), net	(3)	(16)	(12)	(323)
Net loss	$ (4,751)	$ (6,584)	$ (16,664)	$ (13,435)
Net loss per common share – Basic and diluted	$ (0.20)	$ (0.51)	$ (0.75)	$ (1.23)
Weighted average number of common shares outstanding – basic and diluted	24,106	12,945	22,104	10,954

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

(in thousands)

	Nine Months Ended September 30,	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (16,664)	$ (13,435)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	954	1,212
Stock-based compensation and 401(k) match	871	1,212
Fair value adjustment of common stock warrants	(1,957)	(6,384)
Loss / (gain) on sale of equipment	16	(16)
Changes in:		
Prepaid expenses and other current assets	(42)	(32)
Accounts Payable	(299)	286
Accrued expenses	(284)	501
Other assets	174	3
Other liabilities and accrued interest on loan payable	57	(2,011)
Net cash used in operating activities	(17,174)	(18,664)
Cash flows from investing activities:		
Purchase of property and equipment	(88)	(101)
Net cash used in investing activities	(88)	(101)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	22,583	26,727
Repayment of loan payable	–	(8,500)
Repayment of equipment loans and capital lease obligations	(121)	(549)
Net cash provided by financing activities	22,462	17,678
Net increase / (decrease) in cash and cash equivalents	5,200	(1,087)
Cash and cash equivalents – beginning of period	10,211	15,741
Cash and cash equivalents – end of period	$ 15,411	$ 14,654
Supplementary disclosure of cash flows information:		
Interest paid	$ 16	$ 2,115
Non-cash transactions:		
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 care for pulmonary medicine by creating life-saving products for critical care patients with respiratory disease. Our KL_4 surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, lyophilized and aerosolized formulations. Surfactants are produced naturally in the lungs and are essential for breathing. We are also developing proprietary drug delivery technologies to enable efficient, targeted upper-respiratory or alveolar delivery of aerosolized KL_4 surfactant and other inhaled therapies. We believe that our proprietary technologies may make 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_4 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) that was focused primarily on aspects of our fetal rabbit biological activity test (BAT), an important quality control release and stability test for Surfaxin. We completed a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT and, on September 2, 2011, filed with the FDA a Complete Response to the 2009 Complete Response Letter. On September 28, 2011, the FDA notified us that it has established March 6, 2012 as its target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant marketing approval for Surfaxin for the prevention of RDS in premature infants.

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 lyophilized (freeze-dried) KL_4 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 aerosolized KL_4 surfactant that is being developed potentially to obviate the need for endotracheal intubation and conventional mechanical ventilation, two invasive procedures that neonatologists seek to avoid. Since currently approved surfactants are administered through endotracheal intubation and mechanical ventilation, we believe that Aerosurf has the potential to address a significant unmet medical need. If approved, Aerosurf will provide practitioners the ability to administer surfactants using less invasive means, which may result in a potentially significant increase in the number of infants at risk for RDS who could benefit from surfactant therapy.

Aerosurf produces aerosolized KL_4 surfactant using our aerosol delivery technologies: our proprietary capillary aerosol generator (CAG) and our novel ventilator circuit / patient interface connectors. The CAG initially has been designed to produce high volume, low-velocity aerosolized KL_4 surfactant for intra-pulmonary delivery for the prevention and/or treatment of RDS in premature infants. In developing our proprietary ventilator circuit / patient interface connectors for Aerosurf, we focused on developing a patient interface and related componentry suitable for use with our CAG in neonatal intensive care units (NICUs). We believe that our ventilator circuit / patient interface connectors have the potential to benefit all patients receiving ventilatory support who require inhaled therapies in a critical care setting. Accordingly, in July 2011, we announced our intention to develop and seek authority to market our ventilator circuit / patient interface connectors in the United States and the European Union under the trade name Afectair™.

Afectair simplifies the delivery of any inhaled therapy to critical-care patients requiring ventilatory support by introducing the inhaled therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. We are implementing a regulatory and manufacturing plan that, if successful, could position us to initiate the commercial introduction of Afectair in the United States and the European Union in 2012.

In addition to our lead products, as our resources permit, we plan over time to develop our KL_4 surfactant and aerosol drug delivery technologies 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_4 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 capital resources to potentially maximize the inherent value of our technologies. We continue to consider potential financing transactions to meet our capital requirements and continue to fund our operations. We are also seeking to accomplish our objectives through strategic alliances for the development and, if approved, commercialization of our pipeline products. We are engaged in discussions with potential strategic partners who potentially could provide development and commercial expertise as well as financial resources. There can be no assurance, however, that we will successfully conclude any financing, strategic alliance or other similar transaction. Until we secure sufficient financial and strategic resources to support our operations and the continuing development of our KL_4 surfactant and aerosol drug delivery technologies, 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 nine months ended September 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 some or all of these sources. We also believe that anticipated revenue from the commercial introduction of Surfaxin, if approved, and/or Afectair could serve as a potential non-dilutive source of funds to support our research and development activities in the future.

As of September 30, 2011, we had cash and cash equivalents of $15.4 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 November 8, 2011 ($1.79) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $1.8 million. In addition, in connection with our February 2011 public offering, we issued 15-month warrants to purchase five million shares of our common stock at an exercise price of $2.94 per share (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. Through November 8, 2011, we have raised aggregate gross proceeds of $24.8 million, including $23.5 million ($21.6 million net) from a public offering in February 2011 and $1.3 million from financings under our CEFF. 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_4 surfactant for RDS.

Our future capital requirements depend upon many factors, primarily the success of our efforts (i) to gain regulatory approval for Surfaxin in the United States, (ii) to register and execute the commercial introduction of Afectair in the United States and the European union in 2012, (iii) to raise capital through financings and other transactions, and (iv) to secure one or more strategic alliances or other collaboration arrangements to support our product development activities and, if approved, commercialization plans. We anticipate that, at the end of 2011, we will have less than one year's cash available to support our operations. Although we do not currently plan to conduct a significant capital-raising transaction prior to March 6, 2012, the target action date set by the FDA under PDUFA to complete its review and potentially grant marketing approval for Surfaxin for the prevention of RDS in premature infants, we are assessing various forms of financing facilities that would allow us to partially offset cash outflows and raise capital in our discretion from time to time. There can be no assurance, however, that we will not undertake a financing or that we will enter into a financing facility to allow us to partially offset cash outflows. We believe that our ability to enter into financings, strategic alliances and other similar transactions will likely improve if we are able to gain regulatory approval for Surfaxin, initiate the commercial introduction of Afectair, and advance our Surfaxin LS and Aerosurf development programs towards initiation of clinical trials.

If we are unable for any reason to obtain approval for Surfaxin in the United States, or if approval of Surfaxin is delayed for a significant period of time, or if we are unable to introduce Afectair in the United States and European Union markets as planned, we may have difficulty securing additional capital. If we are unable to raise sufficient additional capital, through financing and strategic alternatives, we will likely not have sufficient cash flow and liquidity to fund our business operations, forcing us to curtail our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Even if we succeed in gaining regulatory approvals for, and subsequently commercializing, Surfaxin and Afectair and our other product candidates; in raising additional capital and in securing strategic alliances 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 equity 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 financial and strategic resources to support the continuing development of our KL_4 surfactant and aerosol drug delivery technologies and fund our operations, we will continue to limit investment in our pipeline programs. During 2011, we have continued to manage our expenditures and focus our financial resources on our RDS programs, primarily in support of the potential approval of Surfaxin, and the Afectair program.

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 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 September 30, 2011 and 2010, 14.0 million and 5.2 million shares of common stock, respectively, were potentially issuable upon the exercise of certain stock options and warrants. There also were 128,000 and 119,000 unvested restricted stock awards (RSAs) outstanding as of September 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.

In May 2011, the FASB amended the accounting guidance for fair value to develop common requirements between U.S. Generally Accepted Accounting Principles and International Financial Reporting Standards. The amendments, which are effective for interim and annual periods beginning after December 15, 2011, require entities to (i) provide information about valuation techniques and unobservable inputs used in Level 3 fair value measurements, and (ii) provide a narrative description of the sensitivity of Level 3 measurements to changes in unobservable inputs. The adoption of this update is not expected to have a material impact on the Company's consolidated financial statements.

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 excisable 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 a Fundamental Transaction (as such term is defined 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 September 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 September 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 a 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 November 8, 2011 ($1.79) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $1.8 million. We anticipate using our CEFF (when available) to support our working capital needs and maintain cash availability in 2011.

The financings we have completed under our CEFF in 2011 are as follows:

(in thousands, except per share data)

Completion Date	Shares Issued	Net Proceeds	Discounted Average Price Per Share
January 24, 2011	314	$ 973	$ 3.10
October 10, 2011	35	67	1.93
October 24, 2011	37	61	1.68
November 8, 2011	129	214	1.66
	515	$ 1,315	

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.

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

	Fair Value	Fair value measurement using		
Assets:	September 30, 2011	Level 1	Level 2	Level 3
Money Market	$ 12,877	$ 12,877	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 13,277	$ 13,277	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 8,599	$ –	$ –	$ 8,599

The table below summarizes the activity of Level 3 inputs measured on a recurring basis for the nine months ended September 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	(1,957)
Balance at September 30, 2011	$ 8,599

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 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 September 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	Fair Value of Warrants (in thousands) September 30, 2011
5/13/2009	466,667	$ 17.25	5/13/2014	$ 3,360	$ 289
2/23/2010	916,669	12.75	2/23/2015	5,701	862
2/22/2011	5,000,000	3.20	2/22/2016	8,087	7,448

Changes in the estimated fair value of warrants classified as derivative liabilities are reported in the accompanying 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.

	September 30, 2011	September 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 nine months ended September 30, 2011 and 2010 was as follows:

	Three Months Ended September 30, 2011	Three Months Ended September 30, 2010	Nine Months Ended September 30, 2011	Nine Months Ended September 30, 2010
Research & Development	$ 67	$ 73	$ 203	$ 367
General & Administrative	81	175	309	684
Total	$ 148	$ 248	$ 512	$ 1,051

As of September 30, 2011, there was $0.4 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 1.9 years for stock options and 1.0 year for restricted stock awards.

Note 8 – Contractual Obligations and Commitments

Former Executive Commitment

On July 12, 2011, we entered into a Separation of Employment Agreement and General Release Agreement ("Separation Agreement") with David L. Lopez, Esq., C.P.A., Executive Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer. Pursuant to the Separation Agreement, Mr. Lopez resigned his positions effective July 31, 2011. Under the Separation Agreement, Mr. Lopez is entitled to: (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 for 15,000 shares, subject to continued vesting in accordance with the terms and conditions of his Restricted Stock Agreement ("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. In addition, on February 1, 2012, (i) if not previously paid in full, Mr. Lopez will pay the outstanding aggregate principal and accrued interest on a promissory note issued to us in 2001 (as of September 30, 2011, the outstanding aggregate principal amount of the Note was $170,967), and (ii) we will pay Mr. Lopez $400,000 in separation pay. If Mr. Lopez does not 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. The Separation Agreement also contains a general release of claims by the parties and a 12-month non-competition covenant by Mr. Lopez. In addition, effective as of 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.

The full text of the separation agreement is attached to our Current Report on Form 8-K that we filed with the SEC on July18, 2011.

Note 9 – Subsequent Events

We evaluated all events or transactions that occurred after September 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 were three nonrecognized subsequent events related to financings under our CEFF. *See*, Note 4 – "Stockholders' Equity."

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, and the risk factors discussed in the "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, as well as in 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 care for pulmonary medicine by creating life-saving products for critical care patients with respiratory disease. Our KL_4 surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, lyophilized and aerosolized formulations. Surfactants are produced naturally in the lungs and are essential for breathing. We are also developing proprietary drug delivery technologies to enable efficient, targeted upper-respiratory or alveolar delivery of aerosolized KL_4 surfactant and other inhaled therapies. We believe that our proprietary technologies may make 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_4 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) that was focused primarily on aspects of our fetal rabbit biological activity test (BAT), an important quality control release and stability test for Surfaxin. We completed a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT and, on September 2, 2011, filed with the FDA a Complete Response to the 2009 Complete Response Letter. On September 28, 2011, the FDA notified us that it has established March 6, 2012 as its target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant marketing approval for Surfaxin for the prevention of RDS in premature infants.

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 lyophilized (freeze-dried) KL_4 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 aerosolized KL_4 surfactant that is being developed potentially to obviate the need for endotracheal intubation and conventional mechanical ventilation, two invasive procedures that neonatologists seek to avoid. Since currently approved surfactants are administered through endotracheal intubation and mechanical ventilation, we believe that Aerosurf has the potential to address a significant unmet medical need. If approved, Aerosurf will provide practitioners the ability to administer surfactants using less invasive means, which may result in a potentially significant increase in the number of infants at risk for RDS who could benefit from surfactant therapy.

Aerosurf produces aerosolized KL_4 surfactant using our aerosol delivery technologies: our proprietary capillary aerosol generator (CAG) and our novel ventilator circuit / patient interface connectors. The CAG initially has been designed to produce high volume, low-velocity aerosolized KL_4 surfactant for intra-pulmonary delivery for the prevention and/or treatment of RDS in premature infants. In developing our proprietary ventilator circuit / patient interface connectors for Aerosurf, we focused on developing a patient interface and related componentry suitable for use with our CAG in neonatal intensive care units (NICUs). We believe that our ventilator circuit / patient interface connectors have the potential to benefit all patients receiving ventilatory support who require inhaled therapies in a critical care setting. Accordingly, in July 2011, we announced our intention to develop and seek authority to market our ventilator circuit / patient interface connectors in the United States and the European Union under the trade name Afectair™.

Afectair simplifies the delivery of any inhaled therapy to critical-care patients requiring ventilatory support by introducing the inhaled therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. We are implementing a regulatory and manufacturing plan that, if successful, could position us to initiate the commercial introduction of Afectair in the United States and the European Union in 2012.

In addition to our lead products, as our resources permit, we plan over time to develop our KL_4 surfactant and aerosol drug delivery technologies 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_4 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 capital resources to potentially maximize the inherent value of our technologies. We continue to consider potential financing transactions to meet our capital requirements and continue to fund our operations. We are also seeking to accomplish our objectives through strategic alliances for the development and, if approved, commercialization of our pipeline products. We are engaged in discussions with potential strategic partners who potentially could provide development and commercial expertise as well as financial resources. There can be no assurance, however, that we will successfully conclude any financing, strategic alliance or other similar transaction. Until we secure sufficient financial and strategic resources to support our operations and the continuing development of our KL_4 surfactant and aerosol drug delivery technologies, 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_4 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 June 30, 2011, which we filed with the SEC on August 15, 2011:

- Surfaxin for the Prevention of RDS in Premature Infants
  To file the Complete Response to the 2009 Complete Response Letter that we received from the FDA, we conducted a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT and manufactured additional batches of Surfaxin drug product to generate additional data requested by the FDA. The comprehensive preclinical program and all related analytical and concordance testing were completed and the data incorporated into the Complete Response that we filed on September 2, 2011. On September 28, 2011, the FDA notified us that it had deemed our Complete Response to be complete and had established March 6, 2012 as its target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant marketing approval for Surfaxin for the prevention of RDS in premature infants. 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 are continuing our preclinical activities for both Surfaxin LS and Aerosurf development programs, although the pace of these programs has slowed as we seek to secure strategic and financial resources to support these programs. Among other things, we are engaged in a technology transfer of our Surfaxin LS lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in lyophilized formulations. We believe that we will have to conduct a Phase 3 clinical trial to gain approval for Surfaxin LS in Europe that will also support approval for Surfaxin LS in the U.S. We have recently initiated discussions with the FDA regarding the Surfaxin LS clinical development program and expect to engage in further discussions with the FDA after we have received regulatory guidance with respect to our planned development program in Europe. 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, in the first quarter 2012, we plan 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 ventilator circuit / patient interface connector that simplifies the delivery of inhaled therapies to critical-care patients needing ventilatory support (intermittent mechanical ventilation or continuous positive airway pressure (CPAP)) and requiring inhaled therapies. In July 2011, we announced our intention to market a series of ventilator circuit / patient interface connectors in the United States and the European Union under the trade name Afectair™. We believe that the Afectair series of products has the potential to become a part of the standard of care for use in delivering inhaled therapies to patients receiving ventilatory support in a critical care setting.

Afectair is a series of disposable ventilator circuit / patient interface connectors and related componentry that introduces inhaled therapies 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 nebulizers,
- A subsequent product, Afectair™ Duo, will be designed for use with vibrating mesh nebulizers (VMN), metered dose inhalers (MDI) and potentially other aerosol generator technologies, including our CAG, and
- Each product will be available in two sizes, one for infants and one for pediatric and adult patients.

Intellectual Property

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. Based on this application, national phase applications are currently pending in the United States, Europe and Japan, among other countries. *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

Afectair Studies

Data from performance studies conducted using Afectair have been presented at the 2011 International Society for Aerosols in Medicine (ISAM) Annual Meeting, the 2011 Pediatric Academic Societies (PAS) Annual Meeting. Our plans include a series of studies evaluating the use of Afectair with several inhaled therapies. Data from the first in these studies were announced recently at the American Association for Respiratory Care (AARC) Congress 2011. We anticipate that further studies will be conducted and presented at congresses in late 2011 and beyond.

Manufacturing, Commercialization and Medical Affairs

To manufacture our Afectair products and related components, we expect to rely on contract manufacturers and other service providers who will provide quality systems, packaging and warehousing to support our planned commercialization of Afectair. To reduce the up-front investment required to commercialize Afectair, at least for the first few years, we plan to rely on third-party medical product distributors to support the launch and continued sales of Afectair. We expect to enter into distribution agreements with distributors in each region of the U.S. and in each country in the European Union in which we choose to sell our products. We expect to sell Afectair products to the distributors at an agreed discount to the established retail price and the distributors will then sell directly to hospitals. We plan to support our network of distributors with an in-house medical affairs staff that will be focused on medical information activities, publications and congresses. In future years, we may determine to bring distribution activities in-house. If successful, we potentially could initiate the commercial introduction of Afectair as follows: (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. We believe that, after an up-take period following the introduction of Afectair, peak revenues could potentially be between $50 million and $75 million in the fourth full year of sales, which could occur as early as 2016.

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

Net Loss and Operating Loss

The net loss for the three months ended September 30, 2011 and 2010 was $4.8 million and $6.6 million, respectively. Included in the net loss is the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $1.4 million for the three months ended September 30, 2011 and non-cash expense of $0.4 million for the three months ended September 30, 2010.

The net loss for the nine months ended September 30, 2011 and 2010 was $16.7 million and $13.4 million, respectively. Included in the net loss is the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $2.0 million and $6.4 million for the nine months ended September 30, 2011 and 2010, respectively.

The operating loss for each of the three months ended September 30, 2011 and 2010 was $6.2 million. Excluding non-cash items related to depreciation and stock-based compensation, the operating loss was $5.7 million and $5.6 million for the three months ended September 30, 2011 and 2010, respectively.

The operating loss for the nine months ended September 30, 2011 and 2010 was $18.6 million and $19.5 million, respectively. Excluding non-cash items related to depreciation and stock-based compensation, the operating loss was $17.1 million and $17.4 million for the three months ended September 30, 2011 and 2010, respectively.

Revenue

We did not recognize any revenues for the three months ended September 30, 2011. For the nine months ended September 30, 2011, we recognized revenue of $0.6 million, 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_4 surfactant for RDS. There were no revenues for the three or nine months ended September 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_4 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 nine months ended September 30, 2011 and 2010 are as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
Research and Development Expenses:	**2011**	**2010**	**2011**	**2010**
Manufacturing development	$ 2,606	$ 2,846	$ 8,099	$ 7,492
Development operations	1,181	1,178	3,623	3,778
Direct preclinical and clinical programs	194	703	1,494	1,953
Total Research & Development Expenses	$ 3,981	$ 4,727	$ 13,216	$ 13,223

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.3 million and $0.4 million for the three months ended September 30, 2011 and 2010, respectively; and $1.1 million and $1.3 million for the nine months ended September 30, 2011 and 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_4 surfactant products, in conformance with current good manufacturing practices (cGMP). These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities and analytical services.

Manufacturing development costs decreased $0.2 million for the three months ended September 30, 2011 compared to the same period in 2010. The decrease is primarily due to a reduction in expenses associated with the technology transfer of our Surfaxin LS lyophilized manufacturing process to a third-party contract manufacturer, partially offset by an increase in manufacturing expenses associated with the manufacture of Surfaxin batches needed to respond to the 2009 Complete Response Letter.

Manufacturing development costs increased $0.6 million for the nine months ended September 30, 2011 compared to the same period in 2010. The increase is primarily due to higher manufacturing expenses associated with the manufacture of Surfaxin batches needed to respond to the 2009 Complete Response Letter, partially offset by a reduction in expenses associated with the technology transfer of our Surfaxin LS lyophilized manufacturing process to a third-party contract manufacturer.

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_4 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 ventilator circuit / patient interface connectors, 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_4 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 the nine months ended September 30, 2011 compared to the same periods in 2010. The decrease is primarily due to a reduction in personnel-related costs associated with our ongoing efforts to conserve our 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 $0.5 million in direct preclinical and clinical program expenses for the three months ended September 30, 2011 compared to 2010 is due primarily to a reduction in expenses associated with addressing the matters identified in the 2009 Complete Response Letter.

The decrease of $0.5 million in direct preclinical and clinical program expenses for the nine months ended September 30, 2011 as compared to 2010 is primarily due to expenses incurred in 2010 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 define the requirements for our regulatory planning, including potential trial design requirements, to be ready potentially to initiate our planned clinical trials after 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 affect 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 ventilator circuit / patient interface connectors to potentially introduce Afectair in the U.S. and European markets. These and our other product programs are described in “Overview – Business and KL_4 Pipeline Programs Update,” and in our other periodic filings with the SEC, including our 2010 Form 10-K, “Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine.”

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

- 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. With the potential commercial introduction of both Afectair and Surfaxin in 2012, we believe that we would greatly advance our goal of improving the standard of care for the treatment of patients suffering with a range of respiratory diseases in a critical care setting.

- We have announced our intent to introduce our proprietary ventilator circuit / patient interface connectors as a stand-alone product under the trade name Afectair™. *See,* "– Overview – Business and Pipeline Programs Update – Afectair – A New Pipeline Program" for a description of Afectair and our plans with respect to the potential introduction of Afectair in 2012.

    - The initial development work for Afectair leveraged the research and development activities associated with development of the ventilator circuit / patient interface connectors for Aerosurf. Thus, while the specific investments for Afectair are not readily determinable, they have been fully expensed and reported in our financial statements to date.

    - We believe that relatively modest additional expenditures will be required to complete the development of Afectair and the work necessary to comply with the regulatory requirements for the initial Afectair product in the U.S. and the European Union, and anticipate an investment of between $0.5 and $1 million, which primarily represents the cost of manufacturing sample devices for review by a "Notified Body" to obtain marketing authorization for Afectair in the European Union. A Notified Body is an organization authorized by member states of the European Union to conduct an audit to ensure that our manufacturers and we are in compliance with applicable quality regulations. In 2012, we anticipate an additional investment of between $0.5 million and $1 million to complete the development of the Afectair Duo product, comply with all regulatory requirements, and initiate manufacturing activities.

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 were $2.2 million and $1.5 million for the three months ended September 30, 2011 and 2010, respectively. Included in general and administrative expenses were non-cash charges associated with stock-based compensation and depreciation of $0.1 million and $0.2 million, respectively. General and administrative expenses for the three months ended September 30, 2011also include a one-time charge of $0.4 million related to contractual severance obligations to a former executive officer. *See,* "– Liquidity and Capital Resources – Debt – Contractual Commitments and Obligations." Excluding the severance obligation and stock-based compensation and depreciation, general and administrative expenses increased $0.4 million for the three months ended September 30, 2011 compared to the same period in 2010. The increase is primarily related to a reduction of legal fees in 2010 due to a fee adjustment, and, in 2011, an increase in business development consulting expenses and expenses associated with our 2011 Annual Meeting of Stockholders, which in 2010 occurred in the fourth quarter.

General and administrative expenses were $6.0 million and $6.3 million for the nine months ended September 30, 2011 and 2010, respectively. Included in general and administrative expenses were non-cash charges associated with stock-based compensation and depreciation of $0.4 million and $0.8 million, respectively. General and administration expenses for the nine months ended September 30, 2011 and 2010 included one-time charges of $0.4 million and $1.0 million, respectively, related to certain contractual severance obligations in each period to a former executive officer. Excluding the one-time severance obligations and charges associated with stock-based compensation and depreciation, general and administrative expenses increased $0.7 million for the nine months ended September 30, 2011 compared to the same period in 2010. The increase is primarily related to incentive payments to employees, Afectair market research, and expenses associated with our 2011 Annual Meeting of Stockholders, which in 2010 occurred in the fourth quarter.

With respect to the potential commercial launch of Afectair, we anticipate an additional annual investment of approximately $1 million, starting in 2012, which primarily represents investment in an in-house medical affairs and marketing management capability. We anticipate that our medical affairs personnel will also provide medical education support for Surfaxin, if approved, 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.

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 are classified as derivative liabilities and valued using the Black-Scholes pricing model. The five-year registered warrants that we issued in February 2011 are 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. The change in the fair value of the warrants is included in the consolidated statement of operations as "Change in the fair value of common stock warrant liability." *See*, Notes 5 and 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 was income of $1.4 million and expense of $0.4 million for the three months ended September 30, 2011 and 2010, 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 was of $2.0 million and $6.4 million for the nine months ended September 30, 2011 and 2010, 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 nine months ended September 30, 2011 and 2010 is as follows:

(Dollars in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2011	**2010**	**2011**	**2010**
Interest income	$ 3	$ 3	$ 10	$ 9
Interest expense	(4)	(19)	(15)	(350)
Other income / (expense)	(2)	–	(7)	18
Other income / (expense), net	$ (3)	$ (16)	$ (12)	$ (323)

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 nine months ended September 30, 2011 consists of interest on our equipment financing facilities.

Interest expense for the three and nine months ended September 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 associated with the warrant issued to PharmaBio in October 2006 as consideration for a restructuring of our loan.

The decrease in interest expense for the three and nine months ended September 30, 2011 compared to the same periods in 2010 is due to (i) payment in full in 2010 of all amounts outstanding under our loan with PharmaBio, (ii) full amortization of deferred financing costs associated with warrant issued to PharmaBio in October 2006 in connection with the PharmaBio loan, and (iii) 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 some or all of these sources. We also believe that anticipated revenue from the commercial introduction of Surfaxin, if approved, and/or Afectair could serve as a potential non-dilutive source of funds to support our research and development activities in the future.

Our future capital requirements depend upon many factors, primarily the success of our efforts (i) to gain regulatory approval for Surfaxin in the United States, (ii) to register and execute the commercial introduction of Afectair in the United States and the European union in 2012, (iii) to raise capital through financings and other transactions, and (iv) to secure one or more strategic alliances or other collaboration arrangements to support our product development activities and, if approved, commercialization plans. We anticipate that, at the end of 2011, we will have less than one year's cash available to support our operations. Although we do not currently plan to conduct a significant capital-raising transaction prior to March 6, 2012, the target action date set by the FDA under PDUFA to complete its review and potentially grant marketing approval for Surfaxin for the prevention of RDS in premature infants, we are assessing various forms of financing facilities that would allow us to partially offset cash outflows and raise capital in our discretion from time to time. There can be no assurance, however, that we will not undertake a financing or that we will enter into a financing facility to allow us to partially offset cash outflows. We believe that our ability to enter into financings, strategic alliances and other similar transactions will likely improve if we are able to gain regulatory approval for Surfaxin, initiate the commercial introduction of Afectair, and advance our Surfaxin LS and Aerosurf development programs towards initiation of clinical trials.

If we are unable for any reason to obtain approval for Surfaxin in the United States, or if approval of Surfaxin is delayed for a significant period of time, or if we are unable to introduce Afectair in the United States and European Union markets as planned, we may have difficulty securing additional capital. If we are unable to raise sufficient additional capital, through financing and strategic alternatives, we will likely not have sufficient cash flow and liquidity to fund our business operations, forcing us to curtail our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Even if we succeed in gaining regulatory approvals for, and subsequently commercializing, Surfaxin and Afectair and our other product candidates; in raising additional capital and in securing strategic alliances 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 equity 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 financial and strategic resources to support the continuing development of our KL_4 surfactant and aerosol drug delivery technologies and fund our operations, we will continue to limit investment in our pipeline programs. During 2011, we have continued to manage our expenditures and focus our financial resources on our RDS programs, primarily in support of the potential approval of Surfaxin, and the Afectair program.

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 potential approval of Surfaxin, which we anticipate could occur in the first quarter 2012, regulatory filings and, if successful, 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 September 30, 2011, we had cash and cash equivalents of $15.4 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 November 8, 2011 ($1.79) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $1.8 million. In addition, in connection with our February 2011 public offering, we issued 15-month warrants to purchase five million shares of our common stock at an exercise price of $2.94 per share (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. Through November 8, 2011, we have raised aggregate gross proceeds of $24.8 million, including $23.5 million ($21.6 million net) from a public offering in February 2011 and $1.3 million from financings under our CEFF. 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_4 surfactant for RDS.

In addition, in connection with the February 2011 public offering, we also issued five-year warrants to purchase five million shares of our common stock at an exercise price of $3.20 per share (2011 five-year warrants). The 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 2011 five-year warrants. If we enter into a new financing facility, or other financing or similar transaction, involving the issuance of our common stock at values less than the then-existing exercise price of the 2011 five-year warrants, the exercise price of the 2011 five-year warrants may be adjusted, which could result in the warrants being exercisable at that time. If the holders determine (in their discretion) to exercise the 2011 five-year warrants and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants, we potentially could raise additional capital to support our activities.

As of September 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 million shares of common stock. To ensure that we had sufficient shares of common stock available for issuance to execute on our business strategies in the future, our Board of Directors approved, subject to stockholder approval, the filing of an amendment to our Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 50 million to 100 million. The increase was approved by our stockholders at our Annual Meeting of Stockholders held on October 3, 2011 and the amendment was filed with the State of Delaware on the same day. As of November 8, 2011, of the 100 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, we had available for issuance, and not otherwise reserved for future issuance, approximately 57 million shares of common stock.

Cash Flows

As of September 30, 2011, we had cash and cash equivalents of $15.4 million compared to $10.2 million as of December 31, 2010. Cash outflows before financings for the nine months ended September 30, 2011 consisted of $17.3 million used for ongoing operating activities and $0.1 million used for debt service. Through September 30, 2011, we raised aggregate gross proceeds of $24.8 million, including $23.5 million ($21.6 million net) from a public offering in February 2011 and $1.0 million from financings under our CEFF.

Cash Flows From Operating Activities

Net cash used in operating activities was $17.2 million and $18.7 million for the nine months ended September 30, 2011 and 2010, respectively.

Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items associated with the change in fair value of common stock warrants ($2.0 million and $6.4 million in 2011 and 2010, respectively), stock-based compensation and depreciation expense ($1.5 million and $2.1 million in 2011 and 2010, respectively), and changes in working capital. Cash flows used in operating activities for the nine months ended September 30, 2010 included a one-time payment of $1.1 million to satisfy 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 $88,000 and $101,000 for the nine months ended September 30, 2011 and 2010, respectively.

Cash Flows from Financing Activities

Net cash provided by financing activities was $22.5 million and $17.7 million for the nine months ended September 30, 2011 and 2010, respectively.

Net cash provided by financing activities for the nine months ended September 30, 2011 includes net proceeds of $21.6 million from a 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 the period represents principal payments on our equipment loan and capital lease obligations of $0.1 million.

Net cash provided by financing activities for the nine months ended September 30, 2010 includes net proceeds of $15.1 million from a February 2010 public offering, $9.1 million from a June 2010 public offering, $2.1 million from a securities purchase agreement with PharmaBio, and $0.3 million from draw downs under our 2010 CEFF. Cash used in financing activities for the period represents principal payments under our loan agreement with PharmaBio of $8.5 million and principal payments on our equipment loan and capital lease obligations of $0.5 million.

Committed Equity Financing Facility (CEFF)

As of September 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. 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.

As of September 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 a 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 November 8, 2011 ($1.79) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $1.8 million. We anticipate using the CEFF (when available) to support our working capital needs and maintain cash availability in 2011.

The financings we have completed under our CEFF in 2011 are as follows:

(in thousands, except per share data)

Completion Date	Shares Issued	Net Proceeds	Discounted Average Price Per Share
January 24, 2011	314	$ 973	$ 3.10
October 10, 2011	35	67	1.93
October 24, 2011	37	61	1.68
November 8, 2011	129	214	1.66
	515	$ 1,315	

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) expired in June 2011. 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 September 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 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 excisable 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 a Fundamental Transaction (as such term is defined 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 paid in full all obligations related to the loan as follows: (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."

Equipment Financing Facilities

As of September 30, 2011, the Company had paid in full all amounts owed under a May 2007 Credit and Security Agreement with GE Business Financial Services Inc. (formerly Merrill Lynch Business Financial Services Inc).

As of September 30, 2011, approximately $0.3 million was outstanding ($65,000 classified as current liabilities and $242,000 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 September 2008 from the Machinery and Equipment Loan Fund (MELF Loan). Interest on the principal amount accrues at a fixed rate of five percent (5.0%) per annum.

In addition to customary terms and conditions, the MELF Loan requires us to meet certain job retention and job creation goals in Pennsylvania within a three-year period (Jobs Covenant). If we fail to comply with the Jobs Covenant, the Department, in its discretion, may change the interest rate on the Promissory Note to a fixed rate equal to two percentage points above the current prime rate for the remainder of the term. As of September 30, 2011, the end of the three-year Jobs Covenant period, due to our efforts to conserve resources as we focus on the potential approval of Surfaxin, we had not complied with the Jobs Covenant. However, in response to a request that we filed with the Department for a waiver, the Department has granted us an extension through August 31, 2012 to come into compliance with the Jobs Covenant and has waived any interest adjustment until that date.

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."

Contractual Obligations and Commitments

During the nine-month period ended September 30, 2011, there were no material changes to our contractual obligations and commitments disclosures as set forth in our most recent Annual Report on Form 10-K, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Contractual Obligations", except as noted below.

On July 12, 2011, we entered into a Separation of Employment Agreement and General Release Agreement ("Separation Agreement") with David L. Lopez, Esq., C.P.A., Executive Vice President, General Counsel, Corporate Secretary and Chief Compliance Officer. Pursuant to the Separation Agreement, Mr. Lopez resigned his positions with us effective July 31, 2011. Under the Separation Agreement, Mr. Lopez is entitled to: (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 for 15,000 shares, subject to continued vesting in accordance with the terms and conditions of his Restricted Stock Agreement ("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. In addition, on February 1, 2012, (i) if not previously paid in full, Mr. Lopez will pay the outstanding aggregate principal and accrued interest on a promissory note issued to us in 2001 (as of September 30, 2011, the outstanding aggregate principal amount of the Note was $170,967), and (ii) we will pay Mr. Lopez $400,000 in separation pay. If Mr. Lopez does not 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. The Separation Agreement also contains a general release of claims by the parties and a 12-month non-competition covenant by Mr. Lopez. In addition, effective as of 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 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 September 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

In addition to the risks, uncertainties and other factors set forth below and elsewhere in this Quarterly Report on Form 10-Q, *see*, the "Risk Factors" section contained in our Annual Report on Form 10-K for the year ended December 31, 2010.

If we are unable to obtain approval for Surfaxin in the United States, or if approval of Surfaxin is delayed for a significant period of time, or if we are unable to introduce Afectair in the United States and European Union markets as planned, we may have difficulty securing additional capital.

We believe that our ability to raise additional required capital to support our research and development programs and fund our operations depends in large part upon our ability to gain approval of Surfaxin in the United States. If we are unable for any reason to obtain approval for Surfaxin in the United States, or if approval of Surfaxin is delayed for a significant period of time, or if we are unable to introduce Afectair in the United States and European Union markets as planned, we may have difficulty securing additional capital. If we are unable to raise sufficient additional capital, through financing and strategic alternatives, we will likely not have sufficient cash flow and liquidity to fund our business operations, forcing us to curtail our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. If we are unable to raise additional capital on terms that are favorable to us, that could have a material adverse effect on our ability to continue our research and development programs and fund operations.

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 registrations and/or authorizations and comply with numerous and varying regulatory requirements. We may not obtain foreign regulatory marketing registrations or authorizations on a timely basis, if at all. Marketing registration or authorization by the FDA would not ensure that we could achieve marketing registration or authorization by regulatory agencies in foreign countries. A failure or delay in obtaining marketing registration or authorization in one jurisdiction may have a negative effect on the process in other jurisdictions, including the FDA. The failure to obtain regulatory marketing registration and/or authorization in domestic or foreign jurisdictions could harm our business.

Delays in gaining regulatory marketing registration and/or 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 registration of Afectair is achieved, it may 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 potential revenues. Foreign regulatory authorities may apply different or similar limitations or may refuse to grant any marketing registration or authorization. Consequently, even if we believe that our submissions are sufficient to comply with regulatory marketing requirements for Afectair, the FDA and foreign regulatory authorities may not ultimately grant marketing registration or authorization for commercial sale in any jurisdiction. If Afectair is not registered and listed as expected, 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, exempt 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.

If we are successful in registering Afectair, it will continue to be subject to numerous regulatory requirements and oversight.

After a device is placed on the market, numerous regulatory requirements may apply. These include: (i) continuing product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action; (ii) Quality System Regulation ("QSR"), which is the medical device term for good manufacturing and quality control practices, requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process; (iii) labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication; (iv) medical device reporting regulations, which require that manufacturers to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur; (v) post-approval or post-clearance restrictions or conditions, including post-approval or post-clearance study commitments; (vi) post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and (vii) the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations. In addition to the FDA, the Federal Trade Commission and state authorities also regulate advertising and promotion activities related to medical devices. The costs of complying, or the failure to comply, with any of these regulations could have a material adverse effect on our business and financial results.

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. It is also possible that other federal, state or foreign enforcement authorities will 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 affect 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 of Afectair is authorized, 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 actions 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, under their own initiative, may 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, as well as opinions of thought leaders in the medical community obtained through advisory boards and similar activities. 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 September 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 September 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: November 14, 2011

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

Date: November 14, 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.

Exhibit No.	Description	Method of Filing
3.1	Amended and Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery), as amended by a Certificate of Amendment to the Restated Certificate of Incorporation of Discovery filed on October 3, 2011	Filed herewith.
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.
4.3	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.
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.

Exhibit No	Description	Method of Filing
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 18, 2011.
10.2	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	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, as filed with the SEC on August 15, 2011.
31.1	Certification of Chief Executive Officer (principal executive officer) pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
31.2	Certification of Chief Financial Officer (principal financial officer) pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith.
101	Financial Statements from the Quarterly Report on Form 10-Q of Discovery for the quarter ended September 30, 2011, filed on November 14, 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

Exhibit 3.1

CERTIFICATE OF AMENDMENT TO
THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
DISCOVERY LABORATORIES, INC.

(Pursuant to Section 242 of the General Corporation Law of the State of Delaware)

Discovery Laboratories, Inc. a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Discovery Laboratories, Inc. (the “Corporation”), and that the Corporation was originally incorporated pursuant to the General Corporation Law on November 6, 1992 under the name Ansan, Inc.

2. That thereafter, the Stockholders duly approved the following amendment to the Corporation's Amended and Restated Certificate of Incorporation, as previously amended and the amendment set forth below shall become effective upon the filing and effectiveness pursuant to the General Corporation Law of this of Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Corporation:

The first paragraph of Article FOURTH of the Amended and Restated Certificate of Incorporation is amended and restated to read as follows:

“The total number of shares of all classes of stock which the Corporation shall have authority to issue is 105,000,000, consisting of 100,000,000 shares of Common Stock, par value $.001 per share (the “Common Stock”), and 5,000,000 shares of preferred stock, par value $.001 per share (the “Preferred Stock”).”

3. Except as set forth in this Certificate of Amendment, the Amended and Restated Certificate of Incorporation, as previously amended, remains in full force and effect.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation on this 3rd day of October, 2011.

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

CERTIFICATE OF AMENDMENT TO
THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
DISCOVERY LABORATORIES, INC.

(Pursuant to Section 242 of the General Corporation Law of the State of Delaware)

Discovery Laboratories, Inc. a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Discovery Laboratories, Inc. (the “Corporation”), and that the Corporation was originally incorporated pursuant to the General Corporation Law on November 6, 1992 under the name Ansan, Inc.

2. That at a meeting of the Board of Directors of the Corporation, resolutions were duly adopted setting forth proposed amendments to the Amended and Restated Certificate of Incorporation of the Corporation, declaring said amendments to be advisable and calling a meeting of the stockholders of the Corporation for consideration thereof.

3. That such amendments were duly adopted in accordance with the provisions of Section 242 of the General Corporation Law by the Board of Directors and stockholders of the Corporation, and that such amendments are set forth in this Certificate of Amendment.

4. That upon the effectiveness of this Certificate of Amendment as set forth in paragraph 5 below, Article FOURTH of the Amended and Restated Certificate of Incorporation is amended and restated to read as follows:

> The total number of shares of all classes of stock which the Corporation shall have the authority to issue is 55,000,000 consisting of 50,000,000 shares of common stock, par value $0.001 per share (the “Common Stock”), and 5,000,000 shares of preferred stock, par value $0.001 per share (the “Preferred Stock”).
>
> On December 28, 2010, at 12:01 a.m. Eastern Time (the “Effective Time”), each fifteen (15) shares of the Common Stock, par value $0.001 per share (the “Common Stock”), issued and outstanding immediately prior to the Effective Time shall automatically be combined into one (1) validly issued, fully paid and non-assessable share of Common Stock without any further action by the Corporation or the holder thereof, subject to the treatment of fractional share interests as described below (the “Reverse Stock Split”). No fractional shares will be issued as a result of the Reverse Stock Split. Instead, stockholders who otherwise would be entitled to receive a fractional share of Common Stock as a consequence of the Reverse Stock Split will be entitled to receive cash in an amount equal to the product obtained by multiplying (i) the closing sale price of our Common Stock on the business day immediately preceding the effective date of the Reverse Stock Split as reported on the The Nasdaq Capital Market® by (ii) the number of shares of our Common Stock held by the stockholder that would otherwise have been exchanged for the fractional share interest. Each certificate that immediately prior to the Effective Time represented shares of Common Stock ("Old Certificates"), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional share interests as described above.

5. This Certificate of Amendment shall become effective on December 28, 2010 at 12:01 a.m. Eastern Time.

6. Except as set forth in this Certificate of Amendment, the Amended and Restated Certificate of Incorporation, as previously amended, remains in full force and effect.

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation on this 27th day of December 2010.

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

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

DISCOVERY LABORATORIES, INC.

(Pursuant to Sections 228, 242, and 245 of the
General Corporation Law of the State of Delaware)

The Corporation was originally incorporated on November 6, 1992, under the name "Ansan, Inc."

ARTICLE ONE

The name of the corporation (hereinafter called the "Corporation") is Discovery Laboratories, Inc.

ARTICLE TWO

The address, including street, number, city, and county, of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle; and the name of the registered agent of the Corporation in the State of Delaware at such address is The Corporation Trust Company.

ARTICLE THREE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

ARTICLE FOUR

Authorization. The total number of shares of all classes of stock which the Corporation shall have authority to issue is 385,000,000 consisting of 380,000,000 shares of common stock, par value $.001 per share (the "Common Stock"), and 5,000,000 shares of preferred stock, par value $.001 per share (the "Preferred Stock").

The Board of Directors may divide the Preferred Stock into any number of series, fix the designation and number of shares of each such series, and determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock. The Board of Directors (within the limits and restrictions of any resolutions adopted by it originally fixing the number of any shares of any series of Preferred Stock) may increase or decrease the number of shares initially fixed for any series, but no such decrease shall reduce the number below the number of shares then outstanding and shares duly reserved for issuance.

ARTICLE FIVE

In furtherance and not in limitation of the powers conferred by statute, the Board of Directors shall have the power, both before and after receipt of any payment for any of the Corporation's capital stock, to adopt, amend, repeal or otherwise alter the Bylaws of the Corporation without any action on the part of the stockholders; provided, however, that the grant of such power to the Board of Directors shall not divest the stockholders of nor limit their power to adopt, amend, repeal, or otherwise alter the Bylaws.

ARTICLE SIX

Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

ARTICLE SEVEN

The Corporation reserves the rights to adopt, repeal, rescind or amend in any respect any provisions contained in this Certificate of Incorporation in the manner now or hereafter prescribed by applicable law, and all rights conferred on stockholders herein are granted subject to this reservation.

ARTICLE EIGHT

A director of the Corporation shall, to the fullest extent permitted by the General Corporation Law of the State of Delaware as it now exists or as it may hereafter be amended, not be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Neither any amendment nor repeal of this Article EIGHT, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation inconsistent with this Article EIGHT, shall eliminate or reduce the effect of this Article EIGHT in respect of any matter occurring or any cause of action, suit or claim that, but for this Article EIGHT, would accrue or arise prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE NINE

This Amended and Restated Certificate of Incorporation was duly adopted in accordance with the provisions of Section 245 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, Discovery Laboratories, Inc., has caused this Amended and Restated Certificate of Incorporation to be signed by its duly authorized officer this 9th day of December 2009.

DISCOVERY LABORATORIES, INC.

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

Exhibit 31.1

CERTIFICATIONS

I, W. Thomas Amick, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Discovery Laboratories, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2011

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

Exhibit 31.2

CERTIFICATIONS

I, John G. Cooper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Discovery Laboratories, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2011

/s/ John G. Cooper
John G. Cooper
President and Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended September 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: November 14, 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.