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

FORM 10-Q

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

For the quarterly period ended June 30, 2012

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 July 31, 2012, 43,440,945 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

Table of Contents

PART I - FINANCIAL 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; our financial, clinical, manufacturing and distribution plans and timing and expectations related to commercialization of our of SURFAXIN®, and our AFECTAIR® neonatal device and our products under development, if approved; our expectations, timing and outcomes of submitting regulatory filings for our products under development; our research and development programs for our KL4 surfactant pipeline and our capillary aerosol generator (CAG) and ventilator circuit / patient interface connectors for delivery of aerosolized medications, including planning and development activities, including the timing of any clinical trials and potential development milestones; 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 fail to successfully commercialize SURFAXIN and AFECTAIR, or if SURFAXIN and AFECTAIR do not gain market acceptance for any reason, our revenues would be limited, which could have a material adverse effect on our business, financial condition and results of operations;

- the risk that, if we are unable for any reason to introduce, or if there is a significant delay in the commercial introduction of, SURFAXIN and AFECTAIR in the U.S. and other markets as planned, we may have difficulty securing additional capital to sustain our operations, which could have a material adverse effect on our ability to continue our marketing and distribution efforts, research and development programs and operations;

- risks relating to our plans to develop and secure marketing and distribution capabilities internally and otherwise 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, drug product candidates and drug delivery technologies;

- the risk that we may be unable to enter into strategic alliances or collaboration agreements to support the development of our KL4 surfactant pipeline products, beginning with AEROSURF® (our aerosolized KL4 surfactant using our CAG technology) and SURFAXIN LS™ (our lyophilized (freeze-dried) dosage form of SURFAXIN), and, if approved, commercialization of these products in markets outside the United States;

- risks relating to our ability to develop a successful sales and marketing organization to market SURFAXIN and AFECTAIR and our other product candidates, if approved, in a timely manner, if at all, and that we or our marketing and advertising consultants will not succeed in developing market awareness of our products or that our product candidates will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;

- risks relating to our ability to develop and manufacture drug products based on our KL_4 surfactant technology, drug-device combination products that use our capillary aerosol generator (CAG) technology, and medical devices, including our CAG and novel ventilator circuit / patient interface connectors, for preclinical and clinical studies of our product candidates and for commercialization of our approved products;

- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers and assemblers;

- the risk that we, our contract manufacturers or any of our third-party suppliers, many of which are single-source providers, may encounter problems or delays in manufacturing our drug products, drug product substances, CAG devices and ventilator circuit / patient interface connectors and related componentry, and other materials on a timely basis or in an amount sufficient to support the commercial introduction of SURFAXIN and AFECTAIR devices, as well as our research and development activities for our other product candidates;

- 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) drug and drug-device combination products that we are developing to address RDS in premature infants: AEROSURF and SURFAXIN LS; and (ii) AFECTAIR, our novel ventilator circuit / patient interface connectors;

- 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 or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;

- risks relating to our research and development activities, which among other things involve time-consuming and expensive preclinical studies and potentially multiple clinical trials that may be subject to potentially significant delays or regulatory holds or fail, and that must be conducted using sophisticated and extensive analytical methodologies and quality control release and stability tests to satisfy the requirements of the regulatory authorities;

- 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 retain qualified personnel, which could affect our ability to develop and market our products;

- the risk that market conditions, the competitive landscape or other factors may make it difficult to launch and profitably sell our products;

- risks that reimbursement and health care reform may adversely affect us or that our products will not be accepted by physicians 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 and medical device candidates;

- the risk that we may be unable to maintain compliance with continued listing requirements of The Nasdaq Capital Market® (Nasdaq), which could increase the probability that our stock will be delisted, 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 Committed Equity Financing Facility (CEFF) may be unavailable, for any reason, or may expire or be exhausted, and that additional equity financings could result in substantial equity dilution or result in a downward adjustment to the exercise price of five-year warrants that we issued in February 2011 (which contain price-based anti-dilution revisions);

- 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; and

- other risks and uncertainties detailed in “Risk Factors” and in the documents incorporated by reference in this report.

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

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

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Consolidated Balance Sheets
(in thousands, except per share data)

	June 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 46,008	$ 10,189
Inventory	105	–
Prepaid expenses and other current assets	433	442
Total Current Assets	46,546	10,631
Property and equipment, net	2,235	2,293
Restricted cash	400	400
Total Assets	$ 49,181	$ 13,324
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,335	$ 1,111
Accrued expenses	2,592	2,972
Common stock warrant liability	8,614	6,996
Equipment loans and capitalized leases, current portion	67	68
Total Current Liabilities	12,608	11,147
Equipment loans and capitalized leases, non-current portion	186	224
Other liabilities	686	689
Total Liabilities	13,480	12,060
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 100,000 shares authorized; 43,462 and 24,603 shares issued, 43,441 and 24,582 shares outstanding at June 30, 2012 and December 31, 2011, respectively	43	25
Additional paid-in capital	453,286	401,713
Accumulated deficit	(414,574)	(397,420)
Treasury stock (at cost); 21 shares at June 30, 2012 and December 31, 2011, respectively	(3,054)	(3,054)
Total Stockholders' Equity	35,701	1,264
Total Liabilities & Stockholders' Equity	$ 49,181	$ 13,324

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	**2011**	**2012**	**2011**
Grant Revenue	$ –	$ 201	$ –	$ 582
Expenses:				
Research and development	5,206	4,615	9,739	9,235
Selling, general and administrative	3,610	1,966	5,657	3,786
Total expenses	8,816	6,581	15,396	13,021
Operating loss	(8,816)	(6,380)	(15,396)	(12,439)
Change in fair value of common stock warrant liability	1,680	(1,693)	(1,754)	535
Other income / (expense):				
Interest and other income	2	3	4	7
Interest and other expense	(4)	(6)	(8)	(16)
Other income / (expense), net	(2)	(3)	(4)	(9)
Net loss	$ (7,138)	$ (8,076)	$ (17,154)	$ (11,913)
Net loss per common share – Basic and diluted	$ (0.16)	$ (0.34)	$ (0.49)	$ (0.56)
Weighted average number of common shares outstanding – basic and diluted	43,369	24,027	35,325	21,086

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

(in thousands)

	Six Months Ended June 30,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (17,154)	$ (11,913)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	576	644
Stock-based compensation and 401(k) match	1,109	599
Fair value adjustment of common stock warrants	1,754	(535)
Loss on sale of equipment	–	10
Changes in:		
Inventory	(105)	–
Prepaid expenses and other current assets	9	(14)
Accounts payable	224	301
Accrued expenses	(380)	(313)
Other assets	–	6
Other liabilities and accrued interest	(3)	73
Net cash used in operating activities	(13,970)	(11,142)
Cash flows from investing activities:		
Purchase of property and equipment	(518)	(26)
Net cash used in investing activities	(518)	(26)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	43,605	22,583
Proceeds from exercise of common stock warrants	6,741	–
Repayment of equipment loans and capital lease obligations	(39)	(84)
Net cash provided by financing activities	50,307	22,499
Net increase in cash and cash equivalents	35,819	11,331
Cash and cash equivalents – beginning of period	10,189	10,211
Cash and cash equivalents – end of period	$ 46,008	$ 21,542
Supplementary disclosure of cash flows information:		
Interest paid	$ 7	$ 11

Notes to Consolidated Financial Statements (unaudited)

Note 1 – Organization and Business

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on creating life-saving products for critical care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug technology produces a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing drug delivery technologies potentially to enable efficient delivery of inhaled therapies, including our aerosolized KL_4 surfactant. We believe that our proprietary technologies make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

Our initial strategy is to focus on the development of our KL_4 surfactant and aerosol technologies to improve the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs have the potential to greatly improve the management of RDS and, collectively over time, to become the global standard of care for premature infants with RDS.

On March 6, 2012, the U.S. Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. We are implementing a plan that, if successful, is intended to result in the commercial introduction of SURFAXIN in the United States in the fourth quarter of 2012.

We are building our own specialty commercial and medical affairs organizations to focus on neonatal respiratory critical care. These organizations will execute the commercial launch of SURFAXIN and provide medical and scientific information to the neonatal medical community regarding our proprietary KL_4 surfactant and aerosol drug delivery technologies. We also expect that our commercial and medical affairs organizations will be able to leverage the experience and relationships that we gain from the introduction of SURFAXIN to more effectively support the introductions of our KL_4 surfactant products under development, beginning with AEROSURF® and SURFAXIN LS™, if approved.

AEROSURF is a drug/device combination product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG) and our novel AFECTAIR® ventilator circuit / patient interface connectors. We are developing AEROSURF for premature infants with or at risk for developing RDS. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method. We believe that AEROSURF, if approved, potentially may enable the treatment of a significantly greater number of premature infants at risk for RDS who could benefit from surfactant therapy but who are currently not treated.

Our lyophilized (freeze-dried) dosage form of our KL_4 surfactant is stored as a powder and resuspended to liquid form prior to use. We have a development plan for SURFAXIN LS, with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are engaged in a technology transfer of our lyophilized manufacturing process to a contract manufacturing organization that has expertise in lyophilized products, and plan to manufacture product for use in preclinical and clinical development activities. We are implementing a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States and other major markets worldwide.

AFECTAIR, our novel disposable ventilator circuit / patient interface connector, was initially developed for use with our CAG in the NICU as part of our AEROSURF development program. AFECTAIR devices simplify the delivery of inhaled therapies (including our aerosolized KL_4 surfactant) 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. In February 2012, we successfully registered our AFECTAIR device in the United States as a Class I, exempt medical device. We are implementing a plan that, if successful, is intended to result in the commercial introduction of the AFECTAIR neonatal device for use in the NICU in the United States in the fourth quarter of 2012. To accomplish our objectives, instead of using a broad network of distributors in the United States, we believe that our commercial and medical affairs organizations may more effectively execute the introduction of this product, although we also may work in collaboration with certain distributors to reach all hospitals. With extensive relationships and contacts in the neonatal community, we believe that we are better able to gain important information, develop data, and clearly define the benefits that we expect this product will provide in the care of infants in the NICU.

After we have initiated the launch of the AFECTAIR neonatal device in the United States, we will focus on identifying the optimal approach for introducing our AFECTAIR devices in markets outside the United States. In that regard, we are exploring the various opportunities that may be available to effect the commercial introduction of the AFECTAIR neonatal device in the European Union, including potentially strategic alliances and/or a network of medical device distributors. We currently expect to initiate the launch of the AFECTAIR neonatal device in the European Union in the first half of 2013.

To benefit all critical care patients who require inhaled therapies and who are receiving ventilatory support, in addition to our AFECTAIR neonatal device, we are developing AFECTAIR devices in different sizes, potentially for use in pediatric intensive care units (PICUs) and adult intensive care units (ICUs), and to be compatible with a variety of aerosol generating devices. Our regulatory and manufacturing plan, if successful, is expected to result in the commercial introduction of a second AFECTAIR device, AFECTAIR® DUO, in 2013. We believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients.

An important priority is to secure the strategic resources to support the continued development and commercial introduction of our RDS products. A key goal for us in late 2012 to early 2013 is to secure a significant strategic alliance predominantly focused on the European Union, potentially to share research and development expenses for our AEROSURF and SURFAXIN LS development programs and, if approved, to support the commercial introduction of these products in markets outside the United States. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN in countries where regulatory marketing authorization is facilitated by the recent FDA approval of SURFAXIN in the United States. We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses). There can be no assurance, however, that we will be successful in concluding any strategic alliance, collaboration or other similar transaction.

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 a series of Committed Equity Financing Facilities (CEFFs) and our At-the-Market Program (ATM Program), capital equipment and debt facilities, and strategic alliances.

Our future capital requirements depend upon many factors, primarily the success of our efforts to: (i) execute the commercial introduction of SURFAXIN and AFECTAIR in the United States and other markets, as planned; (ii) secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, commercial introduction of AEROSURF and SURFAXIN LS in markets outside the United States; (iii) advance the AEROSURF and SURFAXIN LS development programs to be in a position to initiate planned Phase 2 and Phase 3 clinical trials, respectively; and (iv) procure the additional capital necessary and desirable to support our activities until such time as the net revenues from our approved products, from potential strategic alliance and collaboration arrangements and from other sources are sufficient to offset cash flow requirements.

As of June 30, 2012, we had cash and cash equivalents of $46.0 million. For the six months ended June 30, 2012, we completed the following financing transactions:

- On March 21, 2012, we completed a public offering of 16,071,429 shares of common stock, resulting in net proceeds to us (after underwriter fees and anticipated expenses) of approximately $42.1 million.
- On March 7, 2012, we delivered a sales notice under our ATM Program to sell shares of common stock. We terminated the offering on March 8, 2012. In connection with that offering, we issued 350,374 shares of our common stock at an aggregate purchase price of approximately $1.6 million, resulting in net proceeds to us of approximately $1.5 million, after deducting commissions due to the sales agent.
- Holders of the 15-month warrants that we issued in February 2011 exercised warrants to purchase 2,238,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million. The remaining 15-month warrants to purchase 2,762,000 shares expired unexercised on May 22, 2012.
- Holders of the five-year warrants that we issued in February 2011 (February 2011 five-year warrants) exercised warrants to purchase 51,250 shares of our common stock at an exercise prices ranging from $2.80 to $3.20 per share, resulting in proceeds to us of $162,000.

As of June 30, 2012, 100 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation and approximately 42.8 million shares of common stock were available for issuance and not otherwise reserved.

To execute our business strategy and fund our operations over time, we anticipate that we may potentially secure additional infusions of capital from a combination of some or all of the following sources:

Upfront and milestone payments and co-funding of development activities associated with potential strategic alliances or other similar transactions:

- We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) to support the development of AEROSURF and SURFAXIN LS and, if approved, the introduction of these products in the European Union and various markets outside the United States.

Secured debt arrangements to fund working capital and/or investment in capital assets:

- In the future, if our efforts are successful, we believe that debt could potentially be a component of our capital structure and financing plans. We could potentially enter into capital equipment financing facilities, revolving working capital lines of credit, term loans and other similar transactions to satisfy our working capital requirements.

In appropriate circumstances, to secure additional capital and strengthen our financial condition, we will also consider equity public offerings and other financing transactions:

- We have a CEFF with Kingsbridge Capital Ltd. (Kingsbridge) that allows us, in our discretion, to raise capital (subject to certain conditions, including volume limitations) at a time and in amounts we deem suitable to support our business plans. Based on the closing market price of our common stock on July 31, 2012 ($2.53) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.6 million. There can be no assurance, however, that the CEFF will be available at any time, or, even if available, that we will utilize the CEFF prior to its expiration in June 2013, or that we will undertake any financings or similar transactions, on favorable terms or otherwise.

In addition, as of June 30, 2012, we had outstanding warrants to purchase approximately 8.0 million shares of our common stock at various prices, exercisable on different dates into 2016. Of these warrants, approximately 4.9 million were February 2011 five-year warrants that were issued at an exercise price of $3.20 per share. These 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. In connection with the March 2012 public offering, the exercise price of these warrants was adjusted downward to $2.80 per share. As of June 30, 2012, 4,948,750 of the February 2011 five-year warrants were outstanding. If the market price of our common stock should exceed $2.80 at any time prior to the expiration date of these warrants (February 2016) and if the holders determine in their discretion to exercise these warrants (and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants), we potentially could raise up to an additional $13.9 million. There can be no assurance, however, that the market price of our common stock will equal or exceed price levels that make exercise of outstanding warrants likely or that holders of outstanding warrants will choose to exercise any or all of their warrants prior to the warrant expiration date.

Although we currently believe that we will be successful in meeting our strategic planning goals, there can be no assurance that we will successfully fund and build our own commercial organization to support the commercial introduction of SURFAXIN and AFECTAIR; that we will successfully execute the launch of SURFAXIN and AFECTAIR within the anticipated time frame, if ever; that the revenues we may realize from the sale of SURFAXIN and AFECTAIR will be in line with current expectations; that we will successfully identify one or more strategic partners or collaboration arrangements to support development and, if approved, commercial introduction of the AEROSURF and SURFAXIN LS product candidates; or that the revenues, if any, that we generate in the future will be sufficient at any time to fund the further development of our research and development programs and support our operations. If we are unable to identify and enter into strategic alliances for the development of AEROSURF and SURFAXIN LS, and if approved, commercialization of AEROSURF and SURFAXIN LS in markets outside the United States, we may be unable to fund planned clinical trials, which would have a material adverse effect on our research and development programs.

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and six months ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. There have been no changes to our critical accounting policies since 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, 2011 that we filed with the Securities and Exchange Commission (SEC) on March 30, 2012, as amended on April 27, 2012 (2011 Form 10-K). Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Inventory

Inventories are determined at the lower of cost or market value with cost determined under the specific identification method. In connection with receipt of the FDA's approval of SURFAXIN and registration of our initial AFECTAIR device in the United States, we assessed the potential capitalization of inventory and the timing of when the related costs were expected to be recoverable through the commercialization of our products. Costs incurred prior to receipt of marketing authorization have been recorded in our statement of operations as research and development expense. As a result, inventory balances and cost of revenue may reflect a lower average per-unit cost of materials for several quarters after we launch our products. As of June 30, 2012, inventories were valued at $0.1 million and consisted of raw materials used in the production of SURFAXIN.

Research and development expense

Research and development expense consists primarily of expenses associated with our personnel, facilities, manufacturing operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred. For the six months ended June 30, 2012, research and development expense includes a $0.5 million charge related to a milestone payment that became payable to Johnson & Johnson (J&J), in accordance with terms of the J&J licensing agreement, upon FDA approval of SURFAXIN.

Net loss per common share

Basic net loss per common share is computed by dividing the net loss by the weighted average number of common shares outstanding for the periods. As of June 30, 2012 and 2011, 11.8 million and 14.0 million shares of common stock, respectively, were potentially issuable upon the exercise of certain stock options and warrants. Due to our net loss, the shares potentially issuable upon the exercise of options and warrants 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 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. We adopted this guidance prospectively effective January 1, 2012 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 June 2011, the FASB issued accounting guidance on comprehensive income. This guidance, which is effective for interim and annual periods beginning after December 15, 2011, is intended to increase the prominence of other comprehensive income in financial statements by presenting it in either a single- or two-statement approach. We adopted this guidance on January 1, 2012, and the adoption did not have a material impact on our consolidated results of operations, financial position or cash flows.

Note 4 – Stockholders' Equity

Registered Public Offerings

On March 21, 2012, we completed a registered public offering of 16,071,429 shares of our common stock, at a price of $2.80 per share resulting in gross proceeds of $45.0 million ($42.1 million net).

At-the-Market Program (ATM Program)

In December 2011, we established our ATM Program with Lazard Capital Markets LLC (Lazard), under which Lazard, our exclusive agent, at our discretion and at such times that we may determine from time to time may sell up to a maximum of $15,000,000 of shares of our common stock over a two-year period ending in December 2013, subject to earlier termination as provided in the related agreement. We agreed to pay Lazard a commission equal to 3.0% of the gross proceeds of any sales of shares. *See*, Note 10 – Stockholders' Equity – Registered Public Offerings and Private Placements – ATM Program, to the consolidated financial statements in our 2011 Form 10-K, for a detailed description of our ATM.

On March 12, 2012, we completed an offering under our ATM Program of 350,374 shares of our common stock for an aggregate purchase price of approximately $1.6 million, resulting in net proceeds to us of approximately $1.5 million, after deducting commissions due to Lazard.

Under the securities laws, our ATM Program is deemed a continuous offering at all times, including when no sales are taking place. We also understand that under the securities regulations, analysts affiliated with brokers and dealers are not permitted to initiate coverage of an issuer's securities while an offering is underway. Since the ATM Program is treated at all times as though an offering is underway, under the regulations an analyst affiliated with Lazard is not permitted to initiate coverage of our stock during the period in which our ATM Program is effective. Therefore, in connection with initiation of coverage of our stock by an analyst affiliated with Lazard, to comply with the applicable securities regulations, we agreed with Lazard to terminate the ATM effective August 6, 2012. This decision was based on a number of factors, including, among others: we did not intend the ATM Program to be the primary source of the capital that we will need to execute our business plan; and we believe that coverage of our stock by well-regarded stock analysts may enhance our market exposure and may improve the trading support that our stock receives in the future. There can be no assurance, however, that other sources of capital will be available on favorable terms when needed, if at all, or that trading in our stock will be affected in any way by such analyst coverage.

Committed Equity Financing Facility (CEFF)

We have a CEFF with Kingsbridge Capital Limited (Kingsbridge), under which, for a period of up to three years ending June 11, 2013, Kingsbridge is committed to purchase, subject to certain conditions, newly issued shares of our common stock. We are not obligated to issue any shares under the CEFF. Our ability to access the CEFF is subject to certain covenants and conditions, including stock price and volume limitations. *See also*, Note 10 – Stockholders' Equity – Registered Public Offerings and Private Placements – Committed Equity Financing Facility (CEFF), to the consolidated financial statements in our 2011 Form 10-K, for a detailed description of our CEFF.

As of June 30, 2012, there were approximately 1.1 million shares potentially available for issuance (up to a maximum of $32.3 million) under the CEFF. Based on the closing market price of our common stock on July 31, 2012 ($2.53) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.6 million.

We have not utilized the CEFF in 2012.

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

Fair Value on a Recurring Basis

The table below categorizes assets and liabilities measured at fair value on a recurring basis as of June 30, 2012 and December 31, 2011:

	Fair Value	Fair value measurement using		
	June 30, 2012	Level 1	Level 2	Level 3
Assets:				
Money Market	$ 39,377	$ 39,377	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 39,777	$ 39,377	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 8,614	$ –	$ –	$ 8,614

	Fair Value	Fair value measurement using		
	December 31, 2011	Level 1	Level 2	Level 3
Assets:				
Money Market	$ 9,377	$ 9,377	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 9,777	$ 9,477	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 6,996	$ –	$ –	$ 6,996

The table below summarizes the activity of Level 3 inputs measured on a recurring basis for the six months ended June 30, 2012 and 2011:

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2011	$ 6,996
Exercise of warrants [1]	(136)
Change in fair value of common stock warrant liability	1,754
Balance at June 30, 2012	$ 8,614

[1] *See*, Note 6 – Common Stock Warrant Liability.

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

The significant unobservable inputs used in the fair value measurement of the May 2009 and February 2010 common stock warrants are the historical volatility of our common stock market price, expected term of the applicable warrants, and the risk-free interest rate based on the U.S. Treasury yield curve in effect at the measurement date. In addition to the significant unobservable inputs noted above, the fair value measurement of the February 2011 five-year warrants also takes into account an assumption of the likelihood and timing of the occurrence of an event that would result in an adjustment to the exercise price in accordance with the anti-dilutive pricing provisions in the warrant. Any significant increases or decreases in the unobservable inputs, with the exception of the risk-free interest rate, would result in significantly higher or lower fair value measurements.

Significant Unobservable Input Assumptions of Level 3 Valuations	June 30, 2012	December 31, 2011
Historical Volatility	79% - 113%	98% - 116%
Expected Term (in years)	1.9 - 3.6	2.4 - 4.2
Risk-free interest rate	0.33% - 0.57%	0.31% - 0.60%

Note 6 – 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,” either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

The registered warrants that we issued in our May 2009 and February 2010 public offerings generally provide that, in the event a related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. Notwithstanding the availability of cashless exercise, under generally accepted accounting principles, these registered warrants are deemed to be subject to potential net cash settlement and must be classified as derivative liabilities because (i) under the federal securities laws, it may not be within our absolute control to provide freely-tradable shares upon exercise of the warrants in all circumstances, and (ii) the warrant agreements do not expressly state 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, 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 February 2011 five-year warrants expressly provide that under no circumstances will we be required to effect a net cash settlement of these warrants. However, these warrants contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the February 2011 five-year warrants. Due to the nature of the anti-dilution provisions, to comply with ASC Topic 815, these warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model.

Selected terms and estimated fair value of warrants accounted for as derivative liabilities at June 30, 2012 are as follows:

Issuance Date	Number of Warrant Shares	Exercise Price	Warrant Expiration Date	Fair Value of Warrants (in thousands)	
				Issuance Date	June 30, 2012
5/13/2009	466,667	$ 17.25	5/13/2014	$ 3,360	$ 37
2/23/2010	916,669	12.75	2/23/2015	5,701	301
2/22/2011	4,948,750	2.80	2/22/2016	8,004	8,276

During the six months ended June 30, 2012, holders of the February 2011 five-year warrants exercised warrants to purchase 51,250 shares of common stock for total proceeds of $162,000. In addition, in accordance with the anti-dilution provisions of the February 2011 five-year warrants, the exercise price of these warrants was adjusted downward in March 2012 from $3.20 per share to the offering price of our March 2012 public offering, $2.80 per share.

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 in our financial statements all stock-based awards to employees and non-employee directors based on their fair value on the date of grant, calculated using the Black-Scholes option-pricing model. Compensation expense related to stock-based awards is recognized ratably over the vesting period, which is typically three years for employees.

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

	June 30, 2012	June 30, 2011
Weighted average expected volatility	110%	112%
Weighted average expected term	4.8 years	4.9 years
Weighted average risk-free interest rate	0.79%	1.47%
Expected dividends	–	–

The total employee stock-based compensation for the three and six months ended June 30, 2012 and 2011 was as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Research & Development	$ 118	$ 73	$ 238	$ 136
Selling, General & Administrative	288	110	566	228
Total	$ 406	$ 183	$ 804	$ 364

As of June 30, 2012, there was $4.8 million of total unrecognized compensation expense related to unvested share-based compensation arrangements granted under our 2011 Long-Term Incentive Plan. That cost is expected to be recognized over a weighted-average vesting period of 2.5 years.

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 for the year ended December 31, 2011 that we filed with the Securities and Exchange Commission (SEC) on March 30, 2012, as amended on April 27, 2012 (2011 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).

OVERVIEW

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on creating life-saving products for critical care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug technology produces a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing drug delivery technologies potentially to enable efficient delivery of inhaled therapies, including our aerosolized KL_4 surfactant. We believe that our proprietary technologies make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

Our initial strategy is to focus on the development of our KL_4 surfactant and aerosol technologies to improve the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs have the potential to greatly improve the management of RDS and, collectively over time, to become the global standard of care for premature infants with RDS.

On March 6, 2012, the U.S. Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. We are implementing a plan that, if successful, is intended to result in the commercial introduction of SURFAXIN in the United States in the fourth quarter of 2012.

We are building our own specialty commercial and medical affairs organizations to focus on neonatal respiratory critical care. These organizations will execute the commercial launch of SURFAXIN and provide medical and scientific information to the neonatal medical community regarding our proprietary KL_4 surfactant and aerosol drug delivery technologies. We also expect that our commercial and medical affairs organizations will be able to leverage the experience and relationships that we gain from the introduction of SURFAXIN to more effectively support the introductions of our KL_4 surfactant products under development, beginning with AEROSURF® and SURFAXIN LS™, if approved.

AEROSURF is a drug/device combination product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG) and our novel AFECTAIR® ventilator circuit / patient interface connectors. We are developing AEROSURF for premature infants with or at risk for developing RDS. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method. We believe that AEROSURF, if approved, potentially may enable the treatment of a significantly greater number of premature infants at risk for RDS who could benefit from surfactant therapy but who are currently not treated.

Our lyophilized (freeze-dried) dosage form of our KL_4 surfactant is stored as a powder and resuspended to liquid form prior to use. We have a development plan for SURFAXIN LS, with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are engaged in a technology transfer of our lyophilized manufacturing process to a contract manufacturing organization that has expertise in lyophilized products, and plan to manufacture product for use in preclinical and clinical development activities. We are implementing a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States and other major markets worldwide.

AFECTAIR, our novel disposable ventilator circuit / patient interface connector, was initially developed for use with our CAG in the NICU as part of our AEROSURF development program. AFECTAIR devices simplify the delivery of inhaled therapies (including our aerosolized KL_4 surfactant) 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. In February 2012, we successfully registered our AFECTAIR device, which is intended for use with jet nebulizers and other aerosol generators, in the United States as a Class I, exempt medical device. We are implementing a plan that, if successful, is intended to result in the commercial introduction of the AFECTAIR neonatal device for use in the NICU in the United States in the fourth quarter of 2012. To accomplish our objectives, instead of using a broad network of distributors in the United States, we believe that our commercial and medical affairs organizations may more effectively execute the introduction of this product, although we also may work in collaboration with certain distributors to reach all hospitals. With extensive relationships and contacts in the neonatal community, we believe that we are better able to gain important information, develop data, and clearly define the benefits that we expect this product will provide in the care of infants in the NICU.

After we have initiated the launch of the AFECTAIR neonatal device in the United States, we will focus on identifying the optimal approach for introducing our AFECTAIR devices in markets outside the United States. In that regard, we are exploring the various opportunities that may be available to effect the commercial introduction of the AFECTAIR neonatal device in the European Union, including potentially strategic alliances and/or a network of medical device distributors. We currently expect to initiate the launch of the AFECTAIR neonatal device in the European Union in the first half of 2013.

To benefit all critical care patients who require inhaled therapies and who are receiving ventilatory support, in addition to our AFECTAIR neonatal device, we are developing AFECTAIR devices in different sizes, potentially for use in pediatric intensive care units (PICUs) and adult intensive care units (ICUs), and to be compatible with a variety of aerosol generating devices. Our regulatory and manufacturing plan, if successful, is expected to result in the commercial introduction of a second AFECTAIR device, AFECTAIR® DUO, in 2013. We believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients.

An important priority is to secure the strategic resources to support the continued development and commercial introduction of our RDS products. A key goal for us in late 2012 to early 2013 is to secure a significant strategic alliance predominantly focused on the European Union, potentially to share research and development expenses for our AEROSURF and SURFAXIN LS development programs and, if approved, to support the commercial introduction of these products in markets outside the United States. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN in countries where regulatory marketing authorization is facilitated by the recent FDA approval of SURFAXIN in the United States. We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses). There can be no assurance, however, that we will be successful in concluding any strategic alliance, collaboration or other similar transaction.

Business and Pipeline Programs Update

The reader is referred to, and encouraged to read in its entirety “Item 1 – Business,” in our 2011 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 2011 Form 10-K:

- SURFAXIN for the Prevention of Respiratory Distress Syndrome (RDS) in Premature Infants at High Risk for RDS

  We are focused on preparations for the commercial introduction of SURFAXIN and remain on track to initiate the launch in the fourth quarter 2012. We have made progress in establishing our own commercial and medical affairs organizations to execute the launch of SURFAXIN in the United States and are in the process of hiring our field-based and other personnel. We plan to work with hospitals that have NICUs to include SURFAXIN on each hospital’s formulary (the approved list of drugs and therapeutics that the hospital will purchase). A hospital’s formulary is usually determined under procedures established by the medical staff and pharmacy department. To maximize formulary adoption, we are also performing development activities to manufacture a second SURFAXIN vial size. In addition, to facilitate proper preparation and administration of SURFAXIN drug product, we plan to make available to hospitals a dry block-warming device called a WARMING CRADLE® that is designed to warm drug vials at the same temperature that is designated in the SURFAXIN prescribing information. Accordingly, we are also working with hospitals to make WARMING CRADLE devices available for use in the NICU.

- AFECTAIR

  AFECTAIR is our disposable ventilator circuit / patient interface connector 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. We have registered our initial AFECTAIR device in the United States and plan to introduce the AFECTAIR neonatal device in the fourth quarter of 2012. We expect that our commercial and medical affairs organizations will support the planned commercial introduction of AFECTAIR in the United States (*see*, SURFAXIN, above). Because we generally expect to market the AFECTAIR neonatal device to the same hospitals to which we plan to market SURFAXIN, we currently expect that our in-house commercial organization will be primarily responsible for the commercial introduction of that device in the Unites States. When other AFECTAIR devices are available for commercial sale, we plan to assess various methods of distributing those products and will determine at that time which approach would be more likely to maximize returns and result in the successful introduction of AFECTAIR. We also continue our efforts to complete development of the follow-on AFECTAIR and AFECTAIR DUO devices, as well as the registration of the initial AFECTAIR device in the European Union. We plan in the future to register our AFECTAIR devices in other major markets worldwide.

- AEROSURF

  To advance our AEROSURF program, we continue our efforts to optimize the design of our CAG with our own engineering staff and third-party medical device experts. On June 22, 2012, we entered into a Research and Development Services Agreement ("Agreement") with Battelle Memorial Institute ("Battelle"). Battelle is the world's largest nonprofit research and development organization, with over 20,000 employees at more than 100 locations globally, with a particular expertise in developing and integrating aerosol devices using innovative and advanced technologies. Pursuant to the Agreement, Battelle will provide technical support and expertise and assist in the development of device components in a series of phased programs focused on design, testing, and manufacturing of clinic-ready CAG devices for our planned AEROSURF phase 2 clinical trials, which we expect to initiate in late 2013. We have retained the authority for all final decisions and all responsibility for the formulation, design, manufacture, assembly, packaging, marketing, distribution and sale of our products. The initial term of the Agreement is two years, unless terminated earlier pursuant to its terms. Either party may terminate the Agreement upon 15 days' written notice to the other party for any good-faith reason, provided, that Battelle does not have the right to terminate the Agreement until it has substantially completed the then-current phase of the project. In addition, Battelle has the right to terminate the Agreement upon 15 days' written notice to us if we are in material breach under the Agreement and the breach is not cured within the 15-day notice period. If fully implemented through all proposed phases, the Agreement could involve an investment by us of up to approximately $4.6 million. If our development work is successful, we plan to seek regulatory guidance for AEROSURF for the United States and Europe, finalize our development strategy and potentially initiate our Phase 2 clinical program after we have secured the necessary strategic alliances and/or capital.

- SURFAXIN LS

  We are also continuing our development activities for our lyophilized KL_4 surfactant, SURFAXIN LS, and plan to advance the technology transfer of our manufacturing process to a third-party contract manufacturer with expertise in lyophilized formulations. We expect to have further interactions with the FDA regarding our SURFAXIN LS development program as well as obtain regulatory guidance with respect to our planned development program in Europe. We expect to initiate our clinical programs for SURFAXIN LS in late 2013, but only after we have developed a final development and regulatory strategy and after we have secured the necessary strategic alliances and/or capital.

For a detailed discussion of our AEROSURF and SURFAXIN LS development programs, *see*, "Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – AEROSURF® for RDS in Premature Infants," and "–SURFAXIN LS™ – Lyophilized SURFAXIN® for RDS in Premature Infants," in our 2011 Form 10-K.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2011. 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 2011 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Inventory

Inventories are determined at the lower of cost or market value with cost determined under the specific identification method. In connection with receipt of the FDA's approval of SURFAXIN® and registration of our initial AFECTAIR® device in the United States, we assessed the potential capitalization of inventory and the timing of when the related costs were expected to be recoverable through the commercialization of our products. Costs incurred prior to receipt of marketing authorization have been recorded in our statement of operations as research and development expense. As a result, inventory balances and cost of revenue may reflect a lower average per-unit cost of materials for several quarters after we launch our products. As of June 30, 2012, inventories were valued at $0.1 million and consisted of raw materials used in the production of SURFAXIN.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the three months ended June 30, 2012 and 2011 was $7.1 million and $8.1 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 $1.7 million for the three months ended June 30, 2012 and non-cash expense of $1.7 million for the three months ended June 30, 2011.

The net loss for the six months ended June 30, 2012 and 2011 was $17.2 million and $11.9 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 expense of $1.8 million and non-cash income of $0.5 million for the six months ended June 30, 2012 and 2011, respectively.

The operating loss for the three months ended June 30, 2012 and 2011 was $8.8 million and $6.4 million, respectively. Included in the operating losses were (i) non-cash items related to depreciation and stock-based compensation of $0.7 million and $0.5 million for 2012 and 2011, respectively; and (ii) in the second quarter of 2011, $0.2 million of grant revenue. Excluding the grant revenue and non-cash items related to depreciation and stock-based compensation, the operating loss was $8.1 million and $6.1 million for 2012 and 2011, respectively.

The operating loss for the six months ended June 30, 2012 and 2011 was $15.4 million and $12.4 million, respectively. Included in the operating losses were (i) in 2012, a $0.5 million charge related to a milestone payment that became payable to Johnson & Johnson (J&J) upon FDA approval of SURFAXIN®, in accordance with terms of the J&J licensing agreement; (ii) non-cash items related to depreciation and stock-based compensation of $1.4 million and $1.0 million for 2012 and 2011, respectively; and (iii) in 2011, $0.6 million of grant revenue. Excluding the J&J milestone payment, grant revenue and non-cash items related to depreciation and stock-based compensation, the operating loss was $13.5 million and $12.0 million for 2012 and 2011, respectively.

Grant Revenue

We did not recognize any revenues for the three and six months ended June 30, 2012. For the three and six months ended June 30, 2011, we recognized grant revenue of $0.2 million and $0.6 million, respectively, for funds received and expended under a Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health to support the development of aerosolized KL_4 surfactant for RDS.

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 and drug delivery technologies, they benefit more than a single project. For that reason, we cannot reasonably estimate the costs or 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) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs.

Research and development expenses for the three and six months ended June 30, 2012 and 2011 are as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
Research and Development Expenses[1]	**2012**	**2011**	**2012**	**2011**
Product development and manufacturing	$ 3,938	$ 3,271	$ 7,041	$ 6,318
Medical and regulatory operations	1,251	869	2,074	1,773
Direct preclinical and clinical programs	17	475	624	1,144
Total Research & Development Expenses	$ 5,206	$ 4,615	$ 9,739	$ 9,235

[1] Certain 2011 expenses have been reclassified to conform to 2012 presentation.

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.4 million and $0.8 million for the three and six months ended June 30, 2012, respectively; and non-cash charges associated with stock-based compensation and depreciation of $0.4 million and $0.7 million for the three and six months ended June 30, 2011, respectively.

Product Development and Manufacturing

Product development and manufacturing includes: (i) the cost of our manufacturing operations, quality assurance and analytical chemistry capabilities to assure adequate production of clinical and commercial drug supply for our KL4 surfactant products, in conformance with current good manufacturing practices (cGMP); (ii) design and development activities related to the development and manufacture of our CAG for use in our preclinical programs, our anticipated clinical programs and, if approved, commercial use; (iii) design and development activities related to our novel ventilator circuit / patient interface connectors, including our AFECTAIR® and AFECTAIR® DUO devices, and; (iv)pharmaceutical development activities, including development of a lyophilized dosage form of our KL4 surfactant. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities, analytical services, and expert consultants and outside services to support pharmaceutical and device development activities.

Product development and manufacturing expenses increased $0.7 million for each of the three and six months ended June 30, 2012, respectively, compared to the corresponding periods in 2011. The increase is primarily due to (i) increased personnel costs to support our manufacturing and quality functions as we prepare for commercial launch of SURFAXIN and the AFECTAIR neonatal device in the fourth quarter of 2012; (ii) employee cash incentive payments; and (iii) increased raw material purchases.

Medical and Regulatory Operations

Medical and regulatory operations includes: (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our research and development programs; and (ii) beginning in 2012, medical affairs activities to provide scientific and medical education support related to both SURFAXIN and AFECTAIR as well as our other KL4 surfactant and aerosol delivery products under development. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Medical and regulatory operations costs have increased $0.4 million and $0.3 million for the three and six months ended June 30, 2012, respectively, over the corresponding periods in 2011. The increase is primarily due to (i) increased personnel costs to support our medical affairs function as we prepare for commercial launch of SURFAXIN and the AFECTAIR neonatal device in the fourth quarter of 2012; and (ii) employee cash incentive payments.

To support the commercial introduction of SURFAXIN and AFECTAIR, we expect to incur expenses at an annual rate of approximately $12-$13 million. We are building our own commercial and medical affairs organizations, which have required an investment in both marketing, field-based sales and medical affairs capabilities. Of this amount, the portion attributed to medical affairs will be charged to Medical and Regulatory Operations. *See also,* "–Results of Operations – Selling, General and Administrative Expenses."

Due to our hiring activities, our personnel costs in 2012 have increased over personnel costs for the same period in 2011. In addition, following the approval of SURFAXIN, we are planning to reinstitute the practice, which had been suspended following receipt of the FDA's 2009 Complete Response Letter, of annually reviewing and awarding employees merit salary increases, cash bonuses and equity incentives. Our Compensation Committee of the Board of Directors is implementing a transition plan to approve new incentive plans and recently granted market and merit-based salary increases, bonus awards and equity incentives to certain officers and employees. *See also*, "– Product Development and Manufacturing," and "– Selling, General and Administrative Expenses."

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) activities related to responding to the complete response letter that we received from the FDA in 2009 (2009 Complete Response Letter); (ii) development activities, including preparatory activities for the anticipated clinical trials for SURFAXIN LS™ and AEROSURF® for RDS in premature infants, toxicology studies and other preclinical studies to obtain data to support potential Investigational New Drug (IND) and new drug application (NDA) filings for our product candidates; and (iii) activities associated with conducting human clinical trials, if any, including patient enrollment costs, external site costs, clinical drug supply and related external costs, such as contract research consultant fees and expenses. See, "Overview – Business and Pipeline Programs Update."

Direct preclinical and clinical programs expense for the three months ended June 30, 2011 includes $0.4 million of costs associated with activities to respond to the 2009 Complete Response Letter.

Direct preclinical and clinical programs expense for the six months ended June 30, 2012 includes a $0.5 million charge related to a milestone payment that became payable to J&J upon FDA approval of SURFAXIN, in accordance with terms of the J&J licensing agreement. The six months ended June 30, 2011 includes $1.0 million of costs associated with activities to respond to the 2009 Complete Response Letter.

We plan to continue to focus our drug research and development activities on the management of RDS in premature infants, specifically our AEROSURF and SURFAXIN LS development programs. To prepare for initiation of our AEROSURF and SURFAXIN LS clinical trials, we plan to obtain regulatory guidance concerning the regulatory requirements for our development plans, including potential clinical trial design requirements. If successful, after we have secured one or more strategic alliances and/or necessary capital, we plan to initiate the AEROSURF Phase 2 clinical program and the SURFAXIN LS Phase 3 clinical program in late 2013. As resources permit, we may make limited investments in non-RDS programs, including potentially acute lung injury (ALI), chronic obstructive pulmonary disorder (COPD) and cystic fibrosis (CF).

Research and Development Projects – Updates

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 the Risk Factors Section of this Quarterly Report on Form 10-Q and in our 2011 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, AEROSURF and SURFAXIN LS; and (ii) development of our aerosol delivery technologies, including our CAG and proprietary AFECTAIR ventilator circuit / patient interface connectors. These and our other product programs are described in "– Overview – Business and Pipeline Programs Update," and in our other periodic filings with the SEC, including our 2011 Form 10-K, "Item 1 – Business – Proprietary Platform – Surfactant and Aerosol Technologies," and "– Surfactant Replacement Therapy for Respiratory Medicine."

In addition to the foregoing and the Pipeline Programs Updates in "– Overview – Business and Pipeline Programs Update" in this MD&A the following are updates related to our research and development programs since the filing of our Form 10-K:

- With respect to SURFAXIN drug product, data from a new pharmacoeconomic analysis were presented at the 2012 Pediatric Academies Society Annual Conference (2012 PAS, April 28 – May 1, 2012) in Boston, MA. The analysis demonstrates that the previously-reported lower rate of reintubation observed in infants treated with SURFAXIN, when compared with infants treated with Curosurf® and Survanta®, also resulted in a potential hospital cost savings of $160,000 to $252,000 per 100 infants. As previously reported in the *Journal of Neonatal- Perinatal Medicine* (Volume 4, Number 2, 2011) in a manuscript entitled "Reintubation and risk of morbidity and mortality in preterm infants after surfactant replacement therapy" (Guardia et al.), retrospective analysis of data from our two large phase 3 trials, which involved a total of 1546 patients, shows that the reintubation rate in SURFAXIN-treated infants ranged from 33 to 35 percent and was significantly lower ($p < 0.05$) than Curosurf-treated infants (47 percent), the current global market leader, and Survanta-treated infants (43 percent). Although the retrospective analysis also demonstrates that reintubation results in an increase in morbidities, such as bronchopulmonary dysplasia and air leak, the estimated cost savings from the pharmacoeconomic modeling reported at the 2012 PAS Conference does not include the additional costs associated with these morbidities. We anticipate that additional studies will be conducted and potentially presented at congresses in 2012 and 2013.

- With respect to SURFAXIN LS, data from a preclinical study of SURFAXIN LS were recently published in the May issue of *Pediatric Research.* The objective of the study was to compare the effects of SURFAXIN LS and Curosurf on pulmonary function, as well as the physiologic reactions to surfactant administration in preterm lambs with RDS. The results of this study, which were previously presented at the 2010 Pediatric Academic Societies Annual Congress in May 2010, demonstrate that both surfactants significantly improved pulmonary function ($p < 0.05$). However, lambs treated with SURFAXIN LS required significantly lower mechanical ventilator pressures to maintain pulmonary function compared with Curosurf-treated lambs ($p < 0.05$); in contrast to lambs treated with SURFAXIN LS, lambs treated with Curosurf experienced significant reductions in heart rate and rapidly increased brain oxygenation during the peridosing period ($p < 0.05$); and the investigators concluded that SURFAXIN LS may enable ventilation at lower mean airway pressures, thereby potentially reducing the incidence of chronic lung disease, and as such may be an effective substitute for the currently-marketed surfactant products.

- With respect to the AFECTAIR series of devices, data from performance studies conducted using the AFECTAIR neonatal device have been presented at 2012 PAS. The study evaluated the difference between the calculated inhaled dose and the actual delivered dose in an *in vitro* simulated infant ventilation system using the AFECTAIR neonatal device as compared to standard of care. Albuterol was aerosolized with a jet nebulizer and delivered using both the AFECTAIR neonatal device and standard of care. The investigators observed a 10-14 fold increase in the *in vitro* inhaled dose of albuterol at various ventilation conditions when using the AFECTAIR neonatal device compared with standard of care. The study concluded that the AFECTAIR neonatal device delivered a higher amount of albuterol *in vitro* that was more representative of the calculated inhaled dose of albuterol compared with standard of care, and that clinical use of the AFECTAIR neonatal device may allow for a more accurate approximation of actual delivered dose of inhaled therapies when targeting a calculated inhaled dose for critical care patients. Data from two studies were presented at the 11th European Congress on Pediatric and Neonatal Ventilation in Switzerland in June 2012. The first study simulated neonatal mechanical ventilation conditions using an *in vitro* model and compared delivery of aerosolized inhaled nitrous oxide using the AFECTAIR neonatal device with standard of care. The study concluded that use of the AFECTAIR neonatal device resulted in the achievement of target nitric oxide concentrations using less nitric oxide when compared to the SoC delivery apparatus. The second study was conducted in an *in vitro* model of neonatal mechanical ventilation conditions and compared the AFECTAIR neonatal device with a conventional wye connector. The study found that use of the AFECTAIR neonatal device resulted in improved delivery of aerosolized albuterol sulfate, including a nine-fold increase in delivered dose under simulated CPAP conditions, a 14-fold increase in delivered dose under simulated mechanical ventilation conditions, and a smaller difference in particle size distribution between aerosol output from the nebulizer and aerosol output from the patient interface.

  With respect to our KL_4 surfactant technology, the United States Patent and Trademark Office (USPTO) granted us a patent entitled "Pulmonary Surfactant Formulations and Methods for Promoting Mucus Clearance." The claims of the patent (U.S. Patent Number 8,221,772) provide coverage for a method for promoting mucus clearance in a patient with a pulmonary condition characterized by excessive mucus secretion or impaired mucus clearance such as CF, COPD, bronchiectasis, ciliary diskinesia, and sinusitis. The patent term expires in September 2027.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of the costs of executive management, marketing and field-based sales, business and commercial development, finance and accounting, intellectual property and legal, human resources, information technology, facility and other administrative costs.

Selling, general and administrative expenses were $3.6 million and $2.0 million for the three months ended June 30, 2012 and 2011, respectively. Included in selling, general and administrative expenses were non-cash charges associated with stock-based compensation and depreciation of $0.3 million and $0.1 million for the three months ended June 30, 2012 and 2011, respectively. Excluding stock-based compensation and depreciation, selling, general and administrative expenses increased $1.4 million for the three months ended June 30, 2012 compared to the same period in 2011. The increase is primarily due to (i) increased personnel costs to support our marketing and field-based sales capabilities as we prepare for the commercial introduction of SURFAXIN and the AFECTAIR neonatal device in the fourth quarter of 2012; and (ii) employee cash incentive payments.

Selling, general and administrative expenses were $5.7 million and $3.8 million for the six months ended June 30, 2012 and 2011, respectively. Included in selling, general and administrative expenses were non-cash charges associated with stock-based compensation and depreciation of $0.6 million and $0.3 million for the six months ended June 30, 2012 and 2011, respectively. Excluding stock-based compensation and depreciation, selling, general and administrative expenses increased $1.5 million for the six ended June 30, 2012 compared to the same period in 2011. The increase is primarily due to (i) increased personnel costs to support our marketing and field-based sales capabilities as we prepare for the commercial introduction of SURFAXIN and the AFECTAIR neonatal device in the fourth quarter of 2012; and (ii) employee cash incentive payments.

In addition to developing our commercial marketing and sales organization, we are planning to make additional investments in the near term to enhance certain of our general and administrative resources, including legal, finance and accounting, and information technologies to support the commercial introduction of SURFAXIN and the AFECTAIR neonatal device in the fourth quarter of 2012. With these investments, we believe that our general and administrative resources will be sufficient to support our business operations.

To support the commercial introduction of SURFAXIN and AFECTAIR, we expect to incur expenses at an annual rate of approximately $12-$13 million. We are building our own commercial and medical affairs organizations, which have required an investment in both marketing, field-based sales and medical affairs capabilities. Of this amount, the portion attributed to marketing and field based sales will be charged to selling, general and administrative expenses. *See also*, "– Medical and Regulatory Operations."

Due to our hiring activities, our personnel costs in 2012 have increased over personnel costs for the same period in 2011. In addition, following the approval of SURFAXIN, we are planning to reinstitute the practice, which had been suspended following receipt of the FDA's 2009 Complete Response Letter, of annually reviewing and awarding employees merit salary increases, cash bonuses and equity incentives. Our Compensation Committee of the Board of Directors is implementing a transition plan to approve new incentive plans and recently granted market and merit-based salary increases, bonus awards and equity incentives to certain officers and employees. *See also*, "– Product Development and Manufacturing," and "– Medical and Regulatory Operations."

We plan to invest in prosecuting and maintaining our existing patent portfolio and trademarks, and in protecting our trade secrets and regulatory exclusivity designations, including potential orphan drug and new drug product exclusivities. We also plan, when appropriate, to invest in potential patent extensions, new patents, new trademarks, and new regulatory exclusivity designations, when available. *See*, "– Research and Development Projects – Updates," above, and in our 2011 Form 10-K, "Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations."

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 have been classified as derivative liabilities and valued using the Black-Scholes pricing model. The five-year registered warrants that we issued in February 2011 (February 2011 five-year warrants) have been 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 fair value of common stock warrant liability for the three months ended June 30, 2012 and 2011 resulted in income of $1.7 million and expense of $1.7 million, respectively, due primarily to changes in our common stock share price during the periods.

The change in the fair value of common stock warrant liability for the six months ended June 30, 2012 and 2011 resulted in expense of $1.8 million and income of $0.5 million, respectively, due primarily to changes in our common stock share price during the periods.

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 a series of Committed Equity Financing Facilities (CEFFs) and our At-the-Market Program (ATM Program), capital equipment and debt facilities, and strategic alliances.

Our future capital requirements depend upon many factors, primarily the success of our efforts to: (i) execute the commercial introduction of SURFAXIN® and AFECTAIR® in the United States and other markets, as planned; (ii) secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, commercial introduction of AEROSURF® and SURFAXIN LS™ in markets outside the United States; (iii) advance the AEROSURF and SURFAXIN LS development programs to be in a position to initiate planned Phase 2 and Phase 3 clinical trials, respectively; and (iv) procure the additional capital necessary and desirable to support our activities until such time as the net revenues from our approved products, from potential strategic alliance and collaboration arrangements and from other sources are sufficient to offset cash flow requirements.

As of June 30, 2012, we had cash and cash equivalents of $46.0 million. For the six months ended June 30, 2012, we completed the following financing transactions:

- On March 21, 2012, we completed a public offering of 16,071,429 shares of common stock, resulting in net proceeds to us (after underwriter fees and anticipated expenses) of approximately $42.1 million.
- On March 7, 2012, we delivered a sales notice under our ATM Program to sell shares of common stock. We terminated the offering on March 8, 2012. In connection with that offering, we issued 350,374 shares of our common stock at an aggregate purchase price of approximately $1.6 million, resulting in net proceeds to us of approximately $1.5 million, after deducting commissions due to the sales agent.
- Holders of the 15-month warrants that we issued in February 2011 exercised warrants to purchase 2,238,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million. The remaining 15-month warrants to purchase 2,762,000 shares expired unexercised on May 22, 2012.
- Holders of the five-year warrants that we issued in February 2011 (February 2011 five-year warrants) exercised warrants to purchase 51,250 shares of our common stock at an exercise prices ranging from $2.80 to $3.20 per share, resulting in proceeds to us of $162,000.

As of June 30, 2012, 100 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation and approximately 42.8 million shares of common stock were available for issuance and not otherwise reserved.

To execute our business strategy and fund our operations over time, we anticipate potentially securing additional infusions of capital from a combination of some or all of the following sources:

Upfront and milestone payments and co-funding of development activities associated with potential strategic alliances or other similar transactions:

- We are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) to support the development of AEROSURF and SURFAXIN LS and, if approved, the introduction of these products in the European Union and various markets outside the United States.

Secured debt arrangements to fund working capital and/or investment in capital assets:

- In the future, if our efforts are successful, we believe that debt could potentially be a component of our capital structure and financing plans. We could potentially enter into capital equipment financing facilities, revolving working capital lines of credit, term loans and other similar transactions to satisfy our working capital requirements.

In appropriate circumstances, to secure additional capital and strengthen our financial condition, we will also consider equity public offerings and other financing transactions:

- We have a CEFF with Kingsbridge Capital Ltd. (Kingsbridge) that allows us, in our discretion, to raise capital (subject to certain conditions, including volume limitations) at a time and in amounts we deem suitable to support our business plans. Based on the closing market price of our common stock on July 31, 2012 ($2.53) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.6 million. There can be no assurance, however, that the CEFF will be available at any time, or, even if available, that we will utilize the CEFF prior to its expiration in June 2013, or that we will undertake any financings or similar transactions, on favorable terms or otherwise.

In addition, as of June 30, 2012, we had outstanding warrants to purchase approximately 8.0 million shares of our common stock at various prices, exercisable on different dates into 2016. Of these warrants, approximately 4.9 million were February 2011 five-year warrants that were issued at an exercise price of $3.20 per share. These 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. In connection with the March 2012 public offering, the exercise price of these warrants was adjusted downward to $2.80 per share. As of June 30, 2012, 4,948,750 of the February 2011 five-year warrants were outstanding. If the market price of our common stock should exceed $2.80 at any time prior to the expiration date of these warrants (February 2016) and if the holders determine in their discretion to exercise these warrants (and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants), we potentially could raise up to an additional $13.9 million. There can be no assurance, however, that the market price of our common stock will equal or exceed price levels that make exercise of outstanding warrants likely or that holders of outstanding warrants will choose to exercise any or all of their warrants prior to the warrant expiration date.

Although we currently believe that we will be successful in meeting our strategic planning goals, there can be no assurance that we will successfully fund and build our own commercial organization to support the commercial introduction of SURFAXIN and AFECTAIR; that we will successfully execute the launch of SURFAXIN and AFECTAIR within the anticipated time frame, if ever; that the revenues we may realize from the sale of SURFAXIN and AFECTAIR will be in line with current expectations; that we will successfully identify one or more strategic partners or collaboration arrangements to support development and, if approved, commercial introduction of the AEROSURF and SURFAXIN LS product candidates; or that the revenues, if any, that we generate in the future will be sufficient at any time to fund the further development of our research and development programs and support our operations. If we are unable to identify and enter into strategic alliances for the development of AEROSURF and SURFAXIN LS, and if approved, commercialization of AEROSURF and SURFAXIN LS in markets outside the United States, we may be unable to fund planned clinical trials, which would have a material adverse effect on our research and development programs.

Cash Flows

As of June 30, 2012, we had cash and cash equivalents of $46.0 million compared to $10.2 million as of December 31, 2011. Cash outflows before financings for the six months ended June 30, 2012 consisted of $14.0 million used for ongoing operating activities, $0.5 million for purchases of property and equipment, and $39,000 used for debt service. Through June 30, 2012, we raised aggregate net proceeds of $50.3 million, including $42.1 million from the March 2012 registered public offering, $6.7 million from warrant exercises, and $1.5 million from a financing under our ATM program.

Cash Flows From Operating Activities

Net cash used in operating activities was $14.0 million and $11.1 million for the six months ended June 30, 2012 and 2011, respectively.

Net cash used in operating activities is the net loss for the period, adjusted for non-cash items associated with the change in fair value of common stock warrants (expense of $1.8 million in 2012 and income of $0.5 million in 2011), stock-based compensation and depreciation expense ($1.7 million and $1.2 million in 2012 and 2011, respectively); and changes in working capital.

The increase in net cash used in operating activities for the six months ended June 30, 2012 compared to the same period in 2011 is primarily due to (i) investments in marketing, field-based sales and medical affairs capabilities as we prepare for commercial launch of SURFAXIN and the AFECTAIR neonatal device in the fourth quarter of 2012; and (ii) the $0.5 million milestone that became payable to J&J upon FDA approval of SURFAXIN.

Cash Flows From Investing Activities

Net cash used in investing activities represents purchases of property and equipment of $0.5 million and $26,000 for the six months ended June 30, 2012 and 2011, respectively. The purchases for the six months ended June 30, 2012 include computer hardware and systems to support our marketing, field-based sales and medical affairs operations, laboratory equipment for our quality and analytical testing operations, and equipment to be used in the commercial manufacturing of AFECTAIR.

Cash Flows from Financing Activities

Net cash provided by financing activities was $50.3 million and $22.5 million for the six months ended June 30, 2012 and 2011, respectively, summarized as follows:

(In millions)	Six Months Ended June 31, 2012	2011
Financings pursuant to common stock offerings	$ 42.1	$ 21.6
Financings under the ATM Program	1.5	–
Exercise of warrants	6.7	–
Financings under the CEFF	–	1.0
Debt service payments	(0.0)	(0.1)
Cash flows from financing activities, net	$ 50.3	$ 22.5

The following sections provide a more detailed discussion of our cash flows from available facilities and activities.

At-the-Market Program (ATM Program)

In December 2011, we entered into a Sales Agency Agreement (Agency Agreement) with Lazard Capital Markets LLC (Lazard), under which Lazard, our exclusive agent, at our discretion and at such times that we may determine from time to time may sell up to a maximum of $15,000,000 of shares of our common stock through an ATM Program. In each sale notice that we issue to Lazard, we may designate the maximum number of shares to be sold, the minimum price per share at which shares may be sold, and other trading parameters. Either Lazard or we may suspend trading activities at any time. The ATM Program had a two-year term, subject to earlier termination as provided in the Agency Agreement. We agreed to pay Lazard a commission equal to 3.0% of the gross proceeds of any sales of shares. *See also*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – ATM Program" in our 2011 Form 10-K.

On March 12, 2012, we completed an offering under out ATM Program of 350,374 shares of our common stock for an aggregate purchase price of approximately $1.6 million, resulting in net proceeds to us of approximately $1.5 million, after deducting commissions due to Lazard under the Agency Agreement.

Under the securities laws, our ATM Program is deemed a continuous offering at all times, including when no sales are taking place. We also understand that under the securities regulations, analysts affiliated with brokers and dealers are not permitted to initiate coverage of an issuer's securities while an offering is underway. Since the ATM Program is treated at all times as though an offering is underway, under the regulations an analyst affiliated with Lazard is not permitted to initiate coverage of our stock during the period in which our ATM Program is effective. Therefore, in connection with initiation of coverage of our stock by an analyst affiliated with Lazard, to comply with the applicable securities regulations, we agreed with Lazard to terminate the ATM effective August 6, 2012. This decision was based on a number of factors, including, among others: we did not intend the ATM Program to be the primary source of the capital that we will need to execute our business plan; and we believe that coverage of our stock by well-regarded stock analysts may enhance our market exposure and may improve the trading support that our stock receives in the future. There can be no assurance, however, that other sources of capital will be available on favorable terms when needed, if at all, or that trading in our stock will be affected in any way by such analyst coverage.

Committed Equity Financing Facility (CEFF)

In June 2011, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), under which, for a period of three years, 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 at the time and in amounts deemed suitable to us. Our ability to access funds is subject to certain conditions, including stock price and volume limitations. We are not obligated to issue any shares under the CEFF. Each draw down under the CEFF is conducted over an eight-day trading period and the volume-weighted average price per share of our common stock (VWAP) on each such 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. The shares issuable under the CEFF are registered under the 2011 Universal Shelf. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility (CEFF)" in our 2011 Form 10-K for a detailed description of our CEFF, including the covenants and conditions that we must meet to use the CEFF.

As of June 30, 2012, there were approximately 1.1 million shares potentially available for issuance (up to a maximum of $32.3 million) under the CEFF. Based on the closing market price of our common stock on July 31, 2012 ($2.53) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.6 million.

We have not utilized the CEFF in 2012.

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. In June 2011, we filed a universal shelf registration statement on Form S-3 (No. 333-174786) (2011 Universal Shelf) with the SEC for the proposed 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. The 2011 Universal Shelf replaced and earlier shelf registration statement that was declared effective by the SEC on June 21, 2008. As of June 30, 2012, $146.4 million remained available for issuance under the 2011 Shelf Registration Statement, before taking account the issuance of shares in connection with the exercise of outstanding warrants, the CEFF and the ATM Program.

Financings under the 2011 Universal Shelf

On March 21, 2012, we completed a public offering of 16,071,429 shares of our common stock at an offering price of $2.80 per share, resulting in gross proceeds of $45.0 million ($42.1 million net). We also granted the underwriters a 30-day option to purchase up to an additional 2,410,714 shares of common stock at an offering price of $2.80, which expired unexercised in April 2012. In connection with this offering, we (and our directors and executive officers) also agreed not to issue or sell (with certain limited exceptions) our securities, including under our ATM Program and CEFF, for a period of 90 days ending June 14, 2012.

See also, "– Liquidity and Capital Resources – At-the-Market (ATM) Program."

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.

Equipment Financing Facilities

Machinery and Equipment Loan Fund

As of June 30, 2012, approximately $0.3 million was outstanding ($67,000 classified as current liabilities and $186,000 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. Due to our efforts to conserve resources while we focused on securing U.S marketing authorization for SURFAXIN, we did not comply with the Jobs Covenant within the three-year period on September 30, 2011. 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 potential interest adjustment until that date.

See, in our 2011 Form 10-K, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt – Equipment Financing Facilities."

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

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

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

Changes in internal controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) under the Exchange Act that occurred during the quarter ended June 30, 2012 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 2011 Form 10-K. Certain of the risk factors in our 2011 Form 10-K are updated below.

Our near-term prospects are highly dependent on the success of SURFAXIN® and AFECTAIR®. To the extent we fail to successfully commercialize SURFAXIN and AFECTAIR, our business, financial condition and results of operations would be materially adversely affected and the price of our common stock would likely decline.

On March 6, 2012, the FDA approved SURFAXIN (lucinactant) for the prevention of RDS in premature infants at high risk for RDS. In February 2012, we successfully registered our initial AFECTAIR device in the United States. We believe that SURFAXIN and AFECTAIR product sales may constitute all or most of our total revenue over the next several years.

The degree of market acceptance and commercial success of SURFAXIN and AFECTAIR and our ability to generate and increase revenues will depend on a number of factors, including the following:

- the number of infants diagnosed with respiratory distress syndrome ("RDS"), and those that may be treated with SURFAXIN over time;
- the number of hospitals and critical care centers that will use AFECTAIR devices for critical care patients;
- the safety and efficacy of SURFAXIN, our ability to provide acceptable evidence of safety and efficacy, and the perceived safety and efficacy of SURFAXIN by the medical community, regulatory agencies and insurers and other payers, on both a short and long-term basis;
- perception of our products and devices by members of the healthcare community, including physicians;
- perceived advantages of SURFAXIN and AFECTAIR over alternative treatment methods (including relative convenience and ease of administration and prevalence and severity of any adverse events, including any unexpected adverse events of which we become aware);
- the acceptance of AFECTAIR devices as the standard of care for delivery of inhaled therapies for patients requiring ventilatory support;
- our ability to finalize our development activities for the pediatric and adult size AFECTAIR devices, and for various types of aerosol generating devices;
- budget impact of adoption of our products and devices on relevant formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs and other competitive products;
- the claims, limitations, warnings and other information in labeling of SURFAXIN;
- our establishment of an effective sales force and the ability of our sales, marketing and other representatives to (a) accurately describe SURFAXIN consistent with its approved labeling and (b) educate critical care providers and hospitals regarding the potential utility of AFECTAIR devices;
- the ability of patients and physicians and other providers to obtain and maintain sufficient coverage and reimbursement by third-party payers, including government payers;
- the receipt and maintenance of marketing approvals from the United States and foreign regulatory authorities;
- the growth of commercial sales in the United States and other countries; and
- the establishment and maintenance of commercial manufacturing capabilities by ourselves or through third-party manufacturers, and our ability to meet commercial demand for SURFAXIN.

SURFAXIN is approved for marketing only in the United States. While we plan to register AFECTAIR in markets outside the United States, beginning with the European Union in 2013, we cannot predict the extent to which AFECTAIR will be utilized in the rest of the world. We cannot predict whether physicians, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize SURFAXIN, AFECTAIR and our other products and devices. Our efforts to educate the medical community and third-party payers regarding the benefits of SURFAXIN and AFECTAIR will require significant resources and may not be successful in achieving our objectives. If SURFAXIN and AFECTAIR do not achieve broad market acceptance, the revenues we generate from sales will be limited and our business may not be profitable.

We may fail in the development and commercialization of our products.

Although we have regulatory clearance to market SURFAXIN and AFECTAIR, they are not currently available for sale and we have no other products approved for marketing. We are implementing a plan intended to result in the commercial introduction of SURFAXIN and AFECTAIR in late 2012. We are conducting further development activities to introduce a second vial size of SURFAXIN, pediatric and adult sized AFECTAIR devices and a second AFECTAIR device, AFECTAIR® DUO. We are also conducting research and development on our other product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products.

We may experience a delay in, or be unable to achieve, the commercial introduction of, SURFAXIN and AFECTAIR in the United States and other markets as planned, or we may not succeed in the development of the second vial size of SURFAXIN or the additional AFECTAIR devices. We may not successfully develop and market our other KL_4 surfactant and aerosol delivery pipeline products. Our long-term viability will be impaired if we experience a significant delay or fail to successfully commercialize our approved products or obtain regulatory approval for, and successfully market, our product candidates. Even if we successfully develop and gain regulatory approval for our products, we still may not generate sufficient or sustainable revenues or we may not become profitable, which could have a material adverse effect on our ability to continue our marketing and distribution efforts, research and development programs and operations.

Generally, before we can attempt to sell products in a hospital, drug products must be approved for addition to that hospital's list of approved drugs, or formulary list, by the hospital's pharmacy and therapeutics (P&T) committee. A hospital's P&T committee typically governs all matters pertaining to the use of medications within the institution, including the review of medication formulary data and recommendations for the appropriate use of drugs within the institution to the medical staff. The frequency of P&T committee meetings at hospitals varies considerably, and P&T committees often require additional information to aid in their decision-making process. Therefore, we may experience substantial delays in obtaining formulary approvals. In addition, our AFECTAIR devices must be approved for use by hospitals' materials management. There can be no assurance that we will successfully gain the required hospital approvals for our products. Additionally, hospitals may be concerned that the cost of acquiring our products for use in their institutions will adversely impact their overall budgets, which could cause resistance to efforts to add our drugs to the formulary and products to the materials list, or to implement restrictions on the usage of our drugs and products in order to control costs. We cannot guarantee that we will be successful in obtaining the approvals we need from enough hospitals quickly enough to optimize hospital sales of SURFAXIN, AFECTAIR or other related products.

In order to facilitate proper preparation and administration of SURFAXIN, we plan to make available to hospitals a WARMING CRADLE® dry block-warming device that is designed to warm drug vials at the same temperature and for the time period that is designated in the SURFAXIN prescribing information. We will need to arrange with each hospital to include WARMING CRADLE on the hospital's list of approved laboratory equipment. There can be no assurance that we will be successful in gaining such approvals.

We may commit substantial efforts, funds and other resources to developing commercially successful medical products. A high rate of failure, or costly delay, is inherent in the development of new medical products. Currently, we are in the process of developing a second vial size for SURFAXIN as well as additional designs of AFECTAIR devices. There can be no assurance that our efforts to develop these products will be successful or that these products will be commercially viable. Failure can occur at any point in the development process, including after significant funds have been invested.

Promising new product candidates may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals, failure to achieve market adoption, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or the infringement of intellectual property rights of others. Even if we successfully develop new products or enhancements or new generations of our existing products, they may be quickly rendered obsolete by newer products, changing customer preferences or changing industry standards. Innovations may not be accepted quickly in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license or otherwise acquire products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete.

Our plan to use strategic alliances and collaboration arrangements to leverage our capabilities may not be successful if we are unable to integrate our partners' capabilities with our operations or if our partners' capabilities do not meet our expectations.

As part of our strategy, we intend to continue to evaluate strategic partnership opportunities and collaboration arrangements. In order for these efforts to be successful, we must first identify partners whose capabilities complement and integrate well with ours. Technologies to which we gain access may prove ineffective or unsafe. Ownership of these technologies may be disputed. The agreements that grant us access to such technologies may expire and may not be renewable or could be terminated if our partners or we do not meet our respective obligations. In addition, our partners may provide certain services for us, such as product development support or distribution services. These agreements are subject to differing interpretations and we and our partners may not agree on the appropriate interpretation of specific requirements. Among other things, our partners may prove difficult to work with, less effective than we originally expected or unable to satisfy their financial and other commitments to us. Failure of our partners to perform as needed could place us at a competitive disadvantage.

If one of our strategic partners or collaborators pursues a product that competes with our products, there could be a conflict of interest and we may not receive expected revenues or milestone or royalty payments.

Certain of our potential strategic partners and collaborators may be developing or marketing a variety of products, some with other partners. Partners or collaborators with whom we enter into distribution agreements may sell and market products that compete with ours, or they may seek to develop, market or sell existing or alternative products or technologies or products targeted at the same diseases or conditions as the products that are the subject of an arrangement with us. Our strategic partners and collaborators may also develop products that are similar to or compete with products they are developing in collaboration with us. If these entities pursue other products instead of our products, we may not receive the anticipated revenues or milestone or royalty payments, or our efforts to distribute our products may be adversely affected.

We may have difficulty managing our growth.

We have experienced and expect to experience significant growth in the scope of our operations as we prepare for the anticipated launch of our products and device in the United States, and thereafter in the European Union and in various markets outside the United States through strategic partnerships. As this potential growth occurs, it has and will continue to place additional significant demands on our management and our financial and operational resources, and will require that we continue to develop and improve our operational, financial and other internal controls. We also are engaged in discussions with potential strategic partners, which, if successful, will require additional management resources and controls to implement and potentially add a layer of complexity to our operations. We plan at various stages of development to distribute our products in the United States, the European Union and various markets outside the United States, through potential strategic alliance and collaboration arrangements. This expansion could further increase the challenges involved in implementing appropriate operational and financial systems, expanding manufacturing capacity and scaling up production, expanding our sales and marketing infrastructure and capabilities and providing adequate training and supervision to maintain high quality standards. We believe that the significant challenges associated with our potential growth will include our ability to recruit, train and integrate skilled sales, marketing, medical affairs, supply chain, administrative and management personnel; to establish strategic partnerships and collaboration arrangements to support our development and commercialization activities, and to provide for manufacturing, including analytical testing and distribution capabilities, for our products, and clinical capabilities for our products under development. Our inability to grow our business appropriately or otherwise adapt to growth would cause our business, financial condition and results of operations to suffer.

The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, healthcare payers and others in the medical community.

Any products that we bring to market, including SURFAXIN and AFECTAIR, may not gain or maintain market acceptance by governmental purchasers, group purchasing organizations, physicians, patients, healthcare payers and others in the medical community. If any products that we develop do not achieve an adequate level of acceptance, we may not generate sufficient revenues to support continued commercialization of these products. The degree of market acceptance of SURFAXIN and AFECTAIR and our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the degree to which the market accepts that we are able to manufacture our products and continually supply the market to meet demand;
- the perceived safety and efficacy of our products;
- the potential advantages over alternative treatments;
- the prevalence and severity of any side effects;
- the relative convenience and ease of administration;
- our ability to gain access to the entire market through our distributor arrangements;
- the rate of preterm births;
- the willingness of physicians to utilize our products;
- the availability of different size drug vials and medical devices to meet the specific needs of healthcare practitioners;
- the pharmacoeconomic benefits (which are determined by comparing, among other things, the cost and effects of a product when compared to different treatment options) and cost-effectiveness of our products;

- the willingness of the target hospitals to accept and employ the WARMING CRADLE dry block heater;
- the effectiveness of our marketing strategy and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

Marketing authorization to promote, manufacture and/or sell AFECTAIR® will be limited and subject to continuing review.

We have successfully registered our initial AFECTAIR device in the United States. We expect to register this device in the European Union in 2013. These registrations do not include substantial claims with respect to potential use or efficacy. Even if regulatory clearance of this product is granted in the European Union, or if regulatory clearance of any subsequent AFECTAIR device is granted, such clearance will be subject to limitations on the 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 clearance has not been obtained. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to serious regulatory enforcement actions, including some of those listed above. It is also possible that other federal, state or foreign enforcement authorities 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 sales and marketing efforts will have to focus only on the general technical attributes and benefits of AFECTAIR and the FDA cleared indications for use. We plan to conduct a series of studies evaluating the utility of AFECTAIR in delivering specific inhaled therapies, but there can be no assurance that our efforts will be successful, or even if successful, that we will be able to expand our label to include the additional indications.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety and/or effectiveness of AFECTAIR devices, and we will have to 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.

We are continually evaluating our business strategy and may modify this strategy in light of developments in our business and other factors.

As we proceed with our plans to commercialize SURFAXIN and AFECTAIR in markets both inside and outside the United States, we will continually evaluate our launch strategy and will modify our plans as necessary to achieve our objectives. The activities associated with introduction of a new product are complex, involve many persons and entities, including third parties that we may not be able to control, and require the coordination of a number of elements, any one of which could involve unforeseen events or circumstances that require adjustment or the development of alternative strategies. If we encounter such events or circumstances, we will change our strategy and plans if we believe that such a change will be in our best interest. For example, if we were to determine that an alternative approach or structure would allow us to maintain control of our products or improve the profitability of our products in one or more markets, we will consider adopting such new approach. Similarly, if a potential partner were to make observations or recommendations concerning the focus, sequence or approach of any or all of our research and development programs, we may consider taking such observations or recommendations into account in our planning process and activities. There can be no assurance, whether or not we alter our strategy or plans for any reason, that we will be successful, or that our product launches will be effectively executed on time, if at all, in all markets that we may identify.

Our ability to discover and develop new products depends on our internal research capabilities and our ability to acquire products. Although we continue to conduct research and development activities on products and have increased our activities in this area, our limited resources may not be sufficient to discover and develop new product candidates. To assist us with the development of our products and, if approved, commercialization of our products in markets outside the United States, we continue to evaluate potential strategic partnership and collaboration arrangements. However, there can be no assurance that our efforts will be successful or that, even if we identify and enter into any such strategic partnership or collaboration arrangement, that such transactions will be successfully implemented within our expected time frames.

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. With respect to our research and development activities, to respond to changing circumstances, we may, from time to time, refocus our product development efforts on different products or may pace, delay or halt the development of various products. As a result of changes in our strategy, we may also change or refocus our existing drug discovery, development, commercialization and manufacturing activities. This could require changes in our facilities and personnel and restructuring various financial arrangements. There can be no assurances that any product development or other changes that we implement will be successful or that, after implementation of any such changes, that we will not determine to refocus our efforts on new or different objectives.

Our activities are subject to various and complex laws and regulations, and we are susceptible to a changing regulatory environment. Any failure to comply could adversely affect our business, financial condition and results of operations.

Our products and our operations are regulated by numerous government agencies, both inside and outside the United States. Our drug product candidates and medical devices must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. Our facilities and those of our third-party providers must be approved and licensed prior to production and remain subject to inspection at any time thereafter. Failure to comply with the requirements of the FDA or other regulatory authorities, including a failed inspection or a failure in our post-marketing reporting, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of our products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could damage our reputation and have a material adverse effect on our sales. In addition, requirements of the FDA and other regulatory authorities may change; implementing additional compliance requirements may increase our costs, or force us or our third-party providers to suspend production, which could result in a shortage of our approved product or delays in the commercial introduction of our new product candidates, if approved.

With the commercial launch of SURFAXIN and AFECTAIR, we will be required to comply with not only the requirements of the FDA and international regulators, but will also become subject to various federal, state and international laws regulating the sales, marketing, and distribution of healthcare-related products. These laws govern such activities as our relationships with healthcare providers, the promotion of our products, and pricing of prescription drug products and medical devices. The sales and marketing of products and relationships that pharmaceutical and medical device companies have with healthcare providers are under increasing scrutiny by federal, state and foreign government agencies. The FDA and other federal regulators have increased their enforcement activities with respect to the Anti-Kickback Statute, False Claims Act, off-label promotion of products, other healthcare related laws, antitrust and other competition laws. The Department of Justice (DOJ) also has increased its focus on the enforcement of the U.S. Foreign Corrupt Practices Act (FCPA), particularly as it relates to the conduct of pharmaceutical companies. Foreign governments have also increased their scrutiny of pharmaceutical companies' sales and marketing activities and relationships with healthcare providers.

Of particular importance, federal and state anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. These laws can be complicated, are subject to frequent change and may be violated unknowingly. In addition, the absence of guidance for some of these laws and the very few court decisions addressing industry practices increase the likelihood that our practices could be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to the government (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. In addition, a number of states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. Many pharmaceutical, device, and other health care companies have been investigated and prosecuted for alleged violations of these laws. Sanctions under these laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs (including Medicare and Medicaid), criminal fines, and imprisonment. Companies that have chosen to settle these alleged violations have typically paid multi-million dollar fines to the government and agreed to abide by corporate integrity agreements, which often include significant and costly burdens. Under the federal False Claims Act and related state laws, private individuals may bring similar actions. In addition, an increasing number of state laws that require manufacturers to report to the state certain pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the state authorities.

We are refining our comprehensive compliance program, including policies, training and various forms of monitoring, designed to address the sales-and-marketing-related risks set forth above. However, no compliance program can mitigate risk in its entirety. Violations or allegations of violations, of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have a material adverse effect on our business, financial condition and results of operations.

The regulatory approval process for our products is expensive and time-consuming and the outcome is uncertain. We may not obtain required regulatory approvals to commercialize our products.

To test, make and sell our products under development, we must receive regulatory approvals for each product. The FDA and foreign regulators, such as the EMA, extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products. This approval process includes (i) preclinical studies and clinical trials of each drug product candidate and active pharmaceutical ingredient to establish its safety and effectiveness, and (ii) confirmation by the FDA and foreign regulators that we maintain good laboratory and manufacturing practices during testing and manufacturing. Even if favorable data are generated by clinical trials, the FDA or foreign regulator may not accept or approve an NDA or market Authorization Application (MAA) filed for a drug product on a timely basis or at all. *See*, "Item 1 – Business – Government Regulation" in our 2011 Form 10-K.

To gain approval for AEROSURF® and SURFAXIN LS™, we expect to conduct a clinical program and are working to be in a position to initiate a Phase 2 clinical trial for AEROSURF and a Phase 3 clinical trial for SURFAXIN LS in late 2013. We believe that our success in gaining approval for SURFAXIN in the United States may facilitate our efforts to gain regulatory approval for AEROSURF and SURFAXIN LS in the United States, the European Union and other markets around the world. However, there can be no assurance that issues requiring protracted and time-consuming preclinical studies will not arise or that our clinical programs will be concluded successfully. There can be no assurance that we will be successful in gaining regulatory approval for AEROSURF or SURFAXIN LS, if at all, within our expected time frame.

We plan to pursue clinical development in the United States, the European Union and other markets and otherwise market and sell our products in the United States, European Union and other various target markets outside of the United States. To accomplish this objective, we must obtain and maintain regulatory approvals and comply with regulatory requirements in each jurisdiction. To avoid the significant expense and lengthy time required to complete multiple clinical programs, we expect to meet with the FDA and other regulatory authorities to potentially address the requirements of the various regulatory authorities through a single, global clinical program. There can be no assurance that our efforts will be successful. If we are unable to reach agreement with the various regulatory authorities, we may not be able to pursue regulatory approval of our products in all of our target markets.

The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which would preclude us from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of their product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected.

Our clinical trials may be delayed, or fail, which will harm our business.

We completed our Phase 3 clinical trials for SURFAXIN for the prevention of RDS in premature infants and have conducted certain Phase 2 trials for other drug product candidates for other indications. If we successfully advance our other KL_4 surfactant development programs for AEROSURF and SURFAXIN LS for RDS through the initial preclinical phase of development, we plan to conduct Phase 2 clinical trials for AEROSURF and Phase 3 clinical trials for SURFAXIN LS, potentially beginning in late 2013. However, before we will initiate a clinical program, we will have to secure adequate capital to support that activity. Such clinical trials generally take two to five years or more to complete and may be delayed by a number of factors. We may not reach agreement with the FDA or a foreign regulator on the design of any one or more of the clinical studies necessary for approval, or we may be unable to reach agreement on a single trial design that would permit us to conduct a single clinical program. Conditions imposed by the FDA and foreign regulators on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Like many biotechnology companies, even after obtaining promising results in earlier trials or in preliminary findings for such clinical trials, we may suffer significant setbacks in late-stage clinical trials. Data obtained from clinical trials are susceptible to varying interpretations that may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials. The timing and completion of current and planned clinical trials of our product candidates depend on many factors, including the rate at which patients are enrolled. Delays in patient enrollment in clinical trials may occur, which would be likely to result in increased costs, program delays, or both.

Patient enrollment is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility and enrollment criteria for the study;
- the willingness of patients or their parents or guardians to participate in the clinical trial;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

If we succeed in achieving our patient enrollment targets, patients that enroll in our clinical trials could suffer adverse medical events or side effects that are known, such as a decrease in the oxygen level of the blood upon administration, or currently unknown to us. It is also possible that we, our Scientific Advisory Board (SAB), the Data and Safety Monitoring Committee (DSMC), the FDA or foreign regulators could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If our SAB, the DSMC, any regulator or we believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. In addition, clinical trials may be interrupted, delayed or halted, in whole or in part, for reasons other than health and safety concerns, including, among other things, matters related to the design of the study, drug availability, SAB and/or DSMC recommendation, or business reasons.

In addition to our planned clinical programs to support AEROSURF and SURFAXIN LS, we also may initiate or support clinical studies evaluating other KL_4 surfactant pipeline products. All of these clinical trials will be time-consuming and potentially costly. Should we fail to complete our clinical development programs or should such programs yield unacceptable results, such failures would have a material adverse effect on our business.

If the parties we depend on for supplying our active drug substances, materials and excipients as well as manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to manufacture and market our approved products and execute our development plans for our pipeline products. Such delays could adversely impact our operations and financial performance.

We rely on suppliers for our active drug substances, materials and excipients, and third parties for certain manufacturing-related services to manufacture drug product that meets appropriate content, quality and stability standards for use in preclinical programs and clinical trials and, for our approved products, commercial sales. Our ability to manufacture depends upon receiving adequate supplies and related services, which may be difficult or uneconomical to procure. Supply chain or manufacturing interruptions could negatively impact our operations and financial performance. The supply of any of our manufacturing materials may be interrupted because of poor vendor performance or other events outside our control, which may require us, among other things, to identify alternate vendors, which could involve a lengthy process, and result in lost sales and increased expenses.

In some cases, we are dependent upon a single supplier to provide all of our requirements for one or more of our drug substances, materials and excipients or one or more of our drug product device subcomponents, components and subassemblies. To assure compliance with cGMP requirements, we have entered into Quality Agreements with all of our suppliers of active drug substances and related materials. However, we have a requirements contract relating to continued access to active drug substances with only one provider of our drug substances. If we do not maintain manufacturing and service relationships that are important to us and are not able to identify a replacement supplier or vendor or develop our own manufacturing capabilities, our ability to obtain regulatory approval for our products could be impaired or delayed and our costs could substantially increase. Even if we are able to find replacement manufacturers, suppliers and vendors when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. The process of changing a supplier could have an adverse impact on future growth opportunities during the transition period if supplies of drug substances, materials or excipients on hand were insufficient to satisfy demand. Such delays could have a material adverse effect on our development activities and our business.

A catastrophic event at our Warrington, Pennsylvania or Totowa, New Jersey facilities or any of the facilities used by our third party-manufacturers would prevent us from producing many of our drug products candidates and/or medical devices.

Our facilities consist of our headquarters in Warrington, Pennsylvania and our manufacturing facility in Totowa, New Jersey. We maintain our analytical testing and device development laboratories in Warrington, Pennsylvania. Our facility in New Jersey is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only drug manufacturing facility. While we manufacture our SURFAXIN liquid instillate at our facilities in Totowa, NJ, we plan to depend upon third-party manufacturers to manufacture our WARMING CRADLE dry block heater, our lyophilized KL4 surfactant, our AFECTAIR devices and our CAG. All of these products are or will be manufactured at a single facility. If a catastrophic event occurred at any our facilities or at the facilities of any of our third-party manufacturers, such as a fire or tornado, many of those products could not be produced until the manufacturing portion of such facility was restored and cleared by the FDA. With respect to our Totowa, New Jersey facility, we maintain a disaster plan to minimize the effects of such a catastrophe, and we have obtained insurance to protect against certain business interruption losses. However, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.

Failure in our information technology systems could disrupt our operations and cause the loss of confidential information, customers and business opportunities.

As we prepare for the commercialization of our first approved products, we will need extensive information technology (IT) systems in virtually all aspects of our business, including billing, customer service, logistics and management of clinical trial and medical data management. In selecting the appropriate software packages and systems to manage and support our activities, we will consider both in-house development and specialty software and system packages offered by third party vendors, service providers and consultants. The systems we select may not be adequate to meet our needs or may fail to perform to the specified requirements. We may be required to seek other sources of system support, which would increase our costs and potentially delay our implementation of necessary activities. There can be no assurance that the systems that we select or choose to develop will be adequate to our needs, that they will perform to our requirements or that we will be successful in integrating them into our operations.

In addition, our technology systems are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Our success will depend, in part, on the continued and uninterrupted performance of our IT systems. IT systems may be vulnerable to damage, disruptions and shutdown from a variety of sources, including telecommunications or network failures, human acts and natural disasters. They also may be subject to physical or electronic intrusions, computer viruses, unauthorized tampering and similar disruptive problems. Likewise, data privacy breaches by employees and others with permitted access to our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. Along with our new systems, we plan to take precautionary measures to prevent unanticipated problems. Nevertheless, we may experience damages to our systems, system failures and interruptions and unauthorized disclosure of confidential information, and our data could be compromised.

There can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition of the company. In addition, there can be no assurances that a significant implementation issue may not arise as we continue to implement new systems and consolidate or replace existing (legacy) systems. If we experience systems problems, or if the systems we implement do not meet our expectations, they may interrupt our ability to operate. If we experience systems problems, or if we experience unauthorized disclosure of confidential information, it could adversely affect our reputation, result in a loss of customers and revenues and cause us to suffer financial damage, including significant costs to alleviate or eliminate the problem.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are implementing our plan to hire additional qualified personnel to support (i) the commercialization of SURFAXIN and AFECTAIR, and (ii) the advancement of our AEROSURF and SURFAXIN LS development programs. In particular, over the second half of 2012, we expect to hire approximately 40 new employees primarily in the areas of field based sales and marketing, medical affairs, and research and development. We expect that the hiring of such additional personnel will increase our annual expenditures by approximately $6.4 million. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is significant and attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us.

We are highly dependent upon the members of our executive management team and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these individuals have been involved with us for many years, have played integral roles in our progress and we believe that they continue to provide value to us. A loss of any of our key personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs.

As of December 31, 2011, we had employment agreements with four executive officers. In February 2012, we provided notice of non-renewal in accordance with these agreements, which expired on May 3, 2012. In addition, we had retention agreements with five other executive officers under which each officer was provided certain severance benefits, based on title. These agreements also expired in May 2012. Effective as of May 4, 2012, we entered into new executive agreements with six executives, including the Chief Executive Officer; the President and Chief Financial Officer; the Senior Vice President and Chief Operating Officer; the Senior Vice President, General Counsel and Corporate Secretary; the Senior Vice President, Human Resources; and the Senior Vice President, Research and Development. In addition, we entered into new retention agreements with five other officers. The loss of services from any of our executives could significantly adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key man life insurance.

As we prepare for the commercialization of our approved products, we will need to attract candidates to join our management, commercial, medical affairs and development teams, although there can be no assurances that we will be successful in that endeavor. We may be unable to attract and retain necessary executive talent. Moreover, the equity incentives, including options and restricted stock, that we have issued are, for the most part, significantly devalued or out of the money and less likely to be exercisable in the future.

To be successful, we believe that it is important to retain our existing key personnel and attract new talent and expertise to execute our business strategy and advance our pipeline programs. Our industry generally seeks to attract and retain executive talent with compensation packages that include a significant equity component. We have recently filed a Definitive Proxy Statement on Schedule 14A, which includes a proposal To amend our 2011 Long-Term Incentive Plan (the “2011 Plan”) to increase the number of shares of Common Stock available for issuance under the 2011 Plan by 2.5 million shares from 3.7 million shares to 6.2 million shares (the “Plan Amendment”). We believe that, if the Plan Amendment is not approved, the shares currently available to provide incentives for current and future employees and consultants will be insufficient to retain the talent and expertise on which we currently rely, and to attract and retain highly-qualified executives and professional and scientific expertise that will be required to accomplish our long-term goals. Without the Plan Amendment, we will not have a sufficient share reserve to attract and retain the necessary marketing, sales and medical affairs talent to execute the launch of SURFAXIN and AFECTAIR, or to retain, reward and attract management and scientific and professional personnel to advance our promising AEROSURF and SURFAXIN LS development programs. If we are unable to attract and retain the talent and expertise that we require, we may be unable to meet our long-term objectives, which would adversely affect our business. There can be no assurance that our stockholders will approve the Plan Amendment and, even if our stockholders approve the Plan Amendment, that we will be able to attract and retain key executive talent and scientific and professional personnel.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel. While we attempt to provide competitive compensation packages to attract and retain key personnel at all levels in our organization, many of our competitors have greater resources and more experience than we do, making it difficult for us to compete successfully for key personnel. We may experience intense competition for qualified personnel and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to lawsuits brought by their former employers.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies intensely in many ways. We need to successfully introduce new products to achieve our strategic business objectives. The development and acquisition of innovative products and technologies that improve efficacy, safety, patients’ and clinicians’ ease of use and cost-effectiveness involve significant technical and business risks. The success of new product offerings will depend on many factors, including our ability to properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory approvals on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economic and timely manner, and differentiate our products from those of our competitors. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers’ requirements, our products may become obsolete and our business could suffer

We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

- developing products;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals or products; and
- manufacturing and marketing products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or foreign regulatory approval or commercializing products before us. Our competitors may successfully secure regulatory exclusivities in various markets, which could have the effect of barring us or limiting our ability to market our products in such markets. As we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities that may successfully develop and commercialize products that are more effective or less expensive than our products. As none of our products are available at this time, we currently have limited or no experience in these areas. In addition, developments by our competitors may render our drug product candidates obsolete or noncompetitive.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors frequently aggressively seek patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that therapeutic developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

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

During the six months ended June 30, 2012, we issued 25,000 unregistered shares of common stock to a consultant as compensation for management consulting services rendered over a period of four months. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(2) of the Act. We did not repurchase any shares of our common stock during the quarter ended June 30, 2012.

ITEM 6. EXHIBITS

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

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: August 14, 2012

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

Date: August 14, 2012

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 as of and October 3, 2011	Incorporated by reference to Exhibit 3.1 to Discovery's Form 8-K, as filed with the SEC on October 3, 2011.
3.2	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6, 2004.
3.3	Amended and Restated By-Laws of Discovery, as amended effective September 3, 2009	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on September 4, 2009.
4.1	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 6, 2004.
4.2	Warrant Agreement dated May 22, 2008 by and between Kingsbridge Capital Limited and Discovery	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K as filed with the SEC on May 28, 2008.
4.3	Warrant Agreement dated December 12, 2008 by and between Kingsbridge Capital Limited and Discovery	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 15, 2008.
4.4	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.
4.5	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.
4.6	Warrant Agreement, dated as of April 30, 2010, by and between Discovery and PharmaBio	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
4.7	Warrant Agreement dated June 11, 2010 by and between Kingsbridge Capital Limited and Discovery	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2010.
4.8	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.

Exhibit No.	Description	Method of Filing
4.9	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.
4.10	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-KSB for the year ended December 31, 2010, as filed with the SEC on March 31, 2011.
4.11	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.
4.12	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*	Employment Agreement dated as of May 4, 2012 between Discovery and W. Thomas Amick	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 10, 2012.
10.2*	Employment Agreement dated as of May 4, 2012 between Discovery and John G. Cooper	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 10, 2012.
10.3*	Employment Agreement dated as of May 4, 2012 between Discovery and Thomas F. Miller	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 10, 2012, as amended by Exhibit 10.1 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on May 11, 2012.
10.4+	Research and Development Services Agreement dated June 22, 2010 between Discovery and Battelle Memorial Institute	Filed herewith.
31.1	Certification of Chief Executive Officer and Principal Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
31.2	Certification of Chief Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
32.1	Certification of 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.

Exhibit No.	Description	Method of Filing
101.1	The following consolidated financial statements from the Discovery Laboratories, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of June 30, 2012 (unaudited) and December 31, 2011, (ii) Statements of Operations (unaudited) for the three and six months ended June 30. 2012 and June 30, 2011, (iii) Statements of Cash Flows (unaudited) for the six months ended June 30, 2012 and June 30, 2011, and (v) Notes to consolidated financial statements.	
101.INS	Instance Document	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

+ Confidential treatment requested as to certain portions of this exhibit. Such portions have been redacted and filed separately with the Commission.

* A management contract or compensatory plan or arrangement required to be filed as an exhibit to this quarterly report pursuant to Item 6 of Form 10-Q.

EXHIBIT 10.4

RESEARCH AND DEVELOPMENT SERVICES AGREEMENT

This Agreement, is made and entered into on June 22, 2012 ("Effective Date"), by and between Discovery Laboratories, Inc., having a place of business at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976 ("Discovery") and Battelle Memorial Institute, through its Corporate Operations, having a place of business at 505 King Avenue, Columbus, Ohio 43201 ("Battelle") individually referred to as "Party" or collectively referred to as "Parties."

WHEREAS, Discovery desires to have Battelle support the research and development of Discovery's Clinical Capillary Aerosol Generator (CAG), initially for use in the AEROSURF® Neonatal (NN) program for respiratory distress syndrome (RDS) ("Project Device"), and Battelle desires to perform such services.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein, Battelle agrees to provide to Discovery technical and research services substantially in accordance with Battelle's Proposal No. OPP106184 (the "Project") attached hereto and incorporated herein by reference, under the following terms and conditions:

1. Term, Acceptance of Proposal(s)

The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect for a period of two (2) years unless earlier terminated as provided in Section 11. Discovery's acceptance of Battelle's Proposal(s) and the commencement and timeline of services thereunder shall be as set forth in the respective Proposal(s).

2. Payment

2.1. Payment Terms. Discovery agrees to pay Battelle's charges for labor services and other expenses for performance of the Project, as set forth in separately executed Proposal(s). Unless otherwise specified in the Proposal(s), Battelle will invoice Discovery on a monthly basis, and Discovery shall pay such invoice, within thirty (30) days of the invoice date. Discovery will not be required to reimburse, and Battelle shall not be required to incur any charges in excess of the estimate stated above, unless mutually agreed upon in writing. [***]. Discovery shall submit invoicing instructions to Battelle in accordance with Exhibit A; and Battelle shall invoice Discovery in a form similar to Exhibit B. [***].

2.2. Taxes. Compensation, as set forth in the Proposal(s), shall include current federal, state and local taxes levied in the United States or on the wages paid to Battelle U.S. employees. Any other present or future taxes, duties, tariffs, fees or other charges, including but not limited to excise, import, purchase, sales, use, turnover, added value, consular, gross receipts, gross wages or other assessments imposed by the government of any other country or subdivision thereof shall be the obligation of Discovery. In the event sales tax applies (e.g., prototypes), Battelle will waive such tax if Discovery furnishes a valid tax exemption certificate for the state in which product is shipped. Any such amounts paid by Battelle shall be added to the estimated amount above and paid by Discovery within thirty (30) days of the date of invoice. Payments shall be made in United States Dollars.

3. Intellectual Property

3.1. Discovery Inventions. [***] (2) "Discovery Invention" is defined as (i) Discovery's proprietary aerosol technologies including the devices employed in producing aerosol (currently CAG devices and AFECTAIR® brand devices) that are used in performance of the Project, [***], and (iv) Discovery's pulmonary surfactant used in performance of the Project, alone or in combination with other compounds. For a period of [***] after the termination or expiration of the Project and at Discovery's request and expense, Battelle will provide Discovery with reasonable assistance to obtain patents on Discovery Inventions and to execute all necessary declarations, affidavits and assignments.

3.2. Battelle Inventions. Inventions made in performance of the Project [***] (a "Battelle Invention") are outside the scope of the Project and are retained by Battelle. To the extent that practicing a Battelle Invention interferes with Discovery's freedom to operate while practicing a Discovery Invention, Battelle hereby provides Discovery a [***] license to use such Battelle Invention [***].

3.3. Non-Infringement Representation. Discovery represents that to the best of Discovery's knowledge there is no patent issued to a third party as of the Effective Date of this Agreement that would be infringed by the manufacture, use, or sale of CAG as contemplated by this Agreement. [***].

3.4. No License. No license to the other Party, under any trademark, patent or copyright is either granted or implied by conveying information to that Party. None of the information that may be submitted or exchanged by the respective parties shall constitute any representation, warranty, assurance, guarantee, or inducement by either Party to the other with respect to infringement of trademarks, patents, copyrights or any right of privacy, or other rights of third persons.

3.5. Work Product. For the avoidance of doubt, Discovery shall own [***] outputs and results generated in the performance of the Project, except for such reports, data and other outputs and results that relate to Battelle Inventions.

4. No Endorsement: Public Announcement

Discovery agrees that it will not use or imply Battelle's name or use Battelle's Reports for endorsement of Discovery's products or fund raising without the prior written approval of an officer of Battelle; however, Discovery may use Battelle's name or use Battelle's reports for regulatory reporting without the prior written approval of an officer of Battelle. For the avoidance of doubt, Discovery may use the content of Battelle Reports for commercially reasonable purposes. Battelle agrees that it will not use or imply Discovery's name or use Discovery's name for any purpose without the prior written approval of an officer of Discovery. Notwithstanding the foregoing, if Discovery concludes in good faith that it is necessary or appropriate to file or describe this Agreement or any related agreements or documents, or provide other notification thereof in a periodic or other report to be filed with the Securities and Exchange Commission or other federal, state or international regulatory authority ("Regulatory Authority"), Discovery at its own expense shall request confidential treatment of sensitive provisions of this Agreement, provided such confidential treatment is reasonably available to Discovery. The Parties shall promptly inform each other in the event of any activities or inquiries of any such Regulatory Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis.

5. Confidentiality

5.1. Confidentiality Agreement. The Mutual Confidential Disclosure Agreement between Discovery and Battelle effective December 3, 2010, and its subsequent amendments prior to this Agreement, hereinafter the "CDA") continues in full force and effect and shall govern the Parties' conduct and handling of Confidential Information under this Agreement. The Parties hereby agree to amend the CDA to extend the term thereof through the date that is one year after the expiration or earlier termination of this Agreement.

5.2. Confidential Information. Discovery has provided Battelle with certain information and data related to the Project (the "Confidential Information," as such term is further defined in the CDA). The Parties agree that any and all information, data and device developed in performance of the Project, including Discovery Inventions and Battelle Inventions, constitute Confidential Information and shall be protected in accordance with the terms and conditions of the CDA. Battelle agrees not to disclose the specific results of the Project as may be embodied in reports and correspondence transmitted to Discovery, and not available to the public generally, without Discovery's written consent, except as required by law. If Battelle wishes to use any results, data or information generated during the performance of the Project for purposes of protecting or publicly disclosing Battelle Inventions ("Disclosure"), Battelle shall seek Discovery's written authorization and shall provide Discovery with a written notice and detailed description of the information intended for inclusion in the Disclosure at least ninety (90) days in advance of the Disclosure, or such reasonable time acceptable to Discovery, to allow time for Discovery to make arrangements necessary, or to request that Battelle make reductions or modifications of such results, data or information, to protect Discovery Inventions.

5.3. Battelle Activities. [***].

6. Nature of Services

Discovery agrees that Battelle is an independent contractor and specifically acknowledges that Battelle is a service provider, not a manufacturer, distributor or supplier. Discovery retains all final decision making authority and all responsibility for the formulation, design, manufacture, assembly, packaging, marketing, distribution and sale of Discovery's products, including, without limitation, product labeling, warnings, instructions to users, reporting and for obtaining any governmental or other pre- or post-market approvals (FDA and otherwise), certifications, registrations, licenses, or permits.

7. Warranties; Limitation of Liability

7.1. Warranties. Battelle represents and warrants that it will use commercially reasonable efforts to provide a high standard of professional service. However, Battelle, as a provider of such services, cannot guarantee success, thus Battelle MAKES NO WARRANTY OR GUARANTEE, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY, FOR ANY REPORT, DESIGN, ITEM, SERVICE OR OTHER RESULT TO BE DELIVERED UNDER THIS AGREEMENT.

7.2. Limitations. Discovery assumes responsibility for its use, misuse, or inability to use the Project results. Except as necessary to satisfy Third Party Claims (as defined in Section 8) indemnified hereunder, [***], Battelle's total liability to Discovery and all liabilities arising out of or related to this Agreement [***]. Except for a breach of its confidentiality obligations hereunder and as set forth in the CDA, neither Party shall be liable to the other Party for any indirect, incidental, consequential, special, punitive or exemplary damages in connection with this Agreement or the Project, however caused, under any theory of liability. [***].

8. Indemnities.

8.1. Third Party Claims. Each of the Parties shall defend, indemnify and hold harmless the other Party, its affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents (collectively, the "Indemnified Parties") from and against any and all losses, costs, damages, fees, liabilities, or expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") incurred in connection with any third party claim, action or proceeding (a "Third Party Claim") to the extent caused by:

8.1.1. any material breach by the indemnifying Party of any of its representations, warranties, covenants or obligations pursuant to this Agreement; and

8.1.2. any negligence, recklessness, willful misconduct or wrongful intentional acts or omissions of the indemnifying Party, its affiliates, or their officers, directors, employees, contractors, consultants, agents, representatives, or sublicensees in the exercise of any of the indemnifying Party's rights or the performance of any of the indemnifying Party's obligations under this Agreement.

8.2. Additional Discovery Indemnities. In addition to the indemnity set forth in Section 8.1 above, Discovery shall defend, indemnify and hold harmless Battelle, its affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents from and against any and all Losses incurred in connection with any Third Party Claim that [***].

8.3. Product Liability. Notwithstanding the provisions of Sections 8.1, Discovery shall defend, indemnify and hold harmless Battelle, its affiliates and its and their respective directors, officers, employees, consultants, contractors, representatives and agents from and against any and all Losses incurred in connection with any Third Party Claims arising out of or relating to the commercialization, marketing, sale, use, handling, manufacture and/or storage of any Project Device, including any claims that involve death or bodily injury (or allegations thereof) to any individual.

8.4. Indemnification Procedures. In the event that an Indemnified Party is entitled to indemnification under this Agreement, such Indemnified Party shall promptly notify the indemnifying Party in writing of the claim (in reasonable detail); *provided, however,* that failure to give such notification shall not affect the indemnification to be provided hereunder except to the extent the indemnifying Party shall have been actually prejudiced as a result of such failure. As a condition to indemnification under this Agreement, the indemnifying Party, in its discretion and at its expense, may manage and control the defense of the claim and its settlement. The Indemnified Parties shall provide the indemnifying Party with reasonable assistance and cooperation and all material relevant information to support the defense of any indemnified claim, and the indemnifying Party shall reimburse the Indemnified Parties for their reasonable out-of-pocket expense incurred in connection with such assistance and cooperation. The indemnifying Party shall not accept any settlement which imposes liability not covered by the indemnification provided under this Agreement or imposes any obligation on, or otherwise adversely affects, the Indemnified Parties without the prior written consent of the affected Indemnified Parties. The indemnifying Party shall have no obligation to indemnify the Indemnified Parties in connection with any settlement made without the indemnifying Party's written consent. Except for such assistance and cooperation as may reasonably be requested by the indemnifying Party, nothing contained in this section shall require any Indemnified Party to take any action in its own name in defending any claim, action or proceedings; *however*, an Indemnified Party, at its option and expense, may review and comment on the defense of any claim through its own counsel. If (i) in the opinion of counsel for an Indemnified Party, representation of such Indemnified Party by the counsel retained by the indemnifying Party would be inappropriate due to actual or potential differing interests between such Indemnified Party and any other Party represented by such counsel in such proceedings, or (ii) the named parties to any such proceeding (including the impleaded parties) include both the indemnifying Party and the Indemnified Party, and representation of both Parties by the same counsel would be inappropriate in the opinion of the Indemnified Party's counsel due to actual or potential differing interests between them; in any such case, one firm of attorneys separate from the indemnifying Party's counsel may be retained to represent the Indemnified Parties with respect to which a conflict exists at the indemnifying Party's expense. As the Parties intend complete indemnification, all reasonable attorneys' fees and expenses incurred by an Indemnified Party in connection with enforcement of this Section 8 shall also be reimbursed by the indemnifying Party.

9. Insurance

9.1. Product Liability Coverage. If any Project Device developed under this Agreement are used by Discovery in clinical trial(s), prior to the first activity involving human subjects, Discovery, its successor in interest or the then owner of the Project Device, agrees to maintain adequate clinical trials liability insurance coverage in amounts customary and prudent for a responsible entity in its industry in light of the nature of its products. Such insurance shall cover any Discovery products that may be developed in whole or in part based on Battelle's work under this Agreement and used in a clinical trial.

9.2. Commercial Activities. Prior to the commercial sale of any Project Device, Discovery, its successor in interest or the then owner of the Project Device, shall maintain adequate product liability insurance coverage in amounts customary and prudent for a responsible entity in its industry in light of the nature of its product(s). Such insurance shall cover any Discovery products that may be developed in whole or in part based on Battelle's work under this Agreement.

9.3. Insurers. Discovery shall use reasonable commercial efforts to maintain coverage with insurance companies that [***], provided that such insurance is available at commercially reasonable costs. Discovery (or its agents or sublicensees) shall maintain products liability coverage related to the Project Device in all territories (on a country-by-country basis) in which the Device is commercially available and shall name Battelle as an additional insured. Discovery shall maintain such insurance throughout the period of any activity involving human subjects and, if such insurance is on a claims-made basis, for [***] following completion of such activity. Discovery, its successor in interest or the then owner of the Project Device shall provide a certificate of insurance to Battelle evidencing such coverage prior to the first administration to a human subject of the drug product aerosolized using the Project Device. Such certificate shall provide for at least thirty (30) days prior notice to Battelle of any cancellation, non-renewal, or relevant reduction in coverage.

10. Force Majeure

Neither Discovery nor Battelle shall be liable in any way for failure to perform any provision of this Agreement (except payment of monetary obligations) if such failure is caused by any law, rule, or regulation, or any cause beyond the control of the Party in default.

11. Termination

11.1. Early Termination. Either Party shall have the right to terminate this Agreement upon fifteen (15) days' written notice for any good-faith basis; provided, however, that Battelle shall not have the right to terminate this Agreement until it has substantially completed the then-current phase of the Project, determined by reference to the Project Plan. In the event of early termination, Battelle agrees to provide Discovery with all reports, materials, or other deliverable items available as of the effective date of the termination, provided that Discovery is not in default of its payment obligations under this Agreement. In any event, Discovery agrees to pay all charges incurred or committed by Battelle, including reasonable costs of termination, within thirty (30) days of receipt of a final invoice.

11.2. Discovery Material Breach. Notwithstanding the foregoing, Battelle shall have the right to terminate this Agreement upon fifteen (15) days' written notice to Discovery in the event that Discovery is in material breach (which includes but is not limited to failure to make payment of undisputed amounts under this Agreement), and such breach is not cured within such fifteen day period.

12. Regulatory Matters

12.1. General; Quality System. Prior to initiation of development activities as set forth in Phase 2 OPP106184 of this Agreement, Discovery and Battelle shall enter into a Quality Agreement ("Quality Agreement") in such form as is acceptable to both Parties. In conducting activities under this Agreement, each Party shall comply in all material respects with all applicable laws and in accordance with the Quality Agreement, including without limitation, U.S. Food and Drug Administration ("FDA") current Good Manufacturing Practice ("cGMP") requirements set forth in the FDA Quality System Regulations ("QSR") applicable to the design and production of clinical devices under Investigational Device Exemptions , 21 CFR 812. Each Party shall bear its own costs and expenses related to QSR compliance. The termination or expiration of this Agreement shall not relieve either Party of its responsibility to comply in all material respects with any applicable regulatory requirements associated with development and use of the Project Device.

12.2. FDA Debarment Certification. Battelle represents and warrants that, after due inquiry, it has not and will not knowingly employ, contract with or retain any person directly or indirectly to perform services under this Agreement, if such person is debarred by the FDA under 21 USC 335a(k) of the FDA Act or a regulator in the EU under similar laws. Upon written request from Discovery, Battelle shall within five (5) business days confirm in writing that it has complied with the foregoing obligation.

13. U.S. Export Control

Discovery agrees not to export or re-export any goods, services, or information obtained from Battelle without first obtaining an export license, if required by law.

14. Client Furnished Materials

Any device, property, equipment, materials or other tangible property furnished by Discovery for use on this Project shall remain the property of Discovery unless otherwise agreed in writing, and will be governed by a separate agreement. [***]. Discovery will cooperate in providing any operation instructions to Battelle upon request and Battelle may reasonably rely on the information so provided. Battelle shall provide such information as Discovery may reasonable request in connection with Discovery's efforts to secure casualty and other insurance covering any such device, property, equipment, materials or other tangible property furnished by Discovery to Battelle in connection with the Project.

15. Entire Agreement

This Agreement, including any related agreement provided hereunder (including, but not limited to, the Quality Agreement), the Proposal, and the CDA incorporated herein, represents the entire agreement of the parties and terminates and supersedes any prior discussions or understandings, whether written or oral, relating to the subject matter hereof. This Agreement may be modified or amended only by mutual agreement in writing. No course of dealing, usage of trade, waiver, or non-enforcement shall be construed to modify or otherwise alter the terms and conditions of this Agreement. In the event of any conflict or inconsistency between these terms and conditions and the Proposal, these terms and conditions shall control.

16. Dispute Resolution

16.1. Executive Negotiation. In the event of any material dispute, difference, claim, action, demand, request, investigation, controversy, threat or other question arising out of or relating to the interpretation of any provisions of this Agreement or the failure of any Party to perform or comply with any obligations or conditions applicable to such Party pursuant to this Agreement (a "Dispute") shall be settled in accordance with the provisions of this Section 16. In the event of such a Dispute, written notice of the dispute must be provided to the other Party within thirty (30) days of the events giving rise to the Dispute. The Parties shall each designate one member of Senior Management to represent it in a meeting to resolve the Dispute. The designated Senior Managers shall negotiate in good faith to achieve a resolution to the Dispute referred to them, within Thirty (30) days after such notice is received. If the Parties are unable to resolve a Dispute within the referenced time frame, the Parties shall each designate a Senior Executive to represent it in a meeting to resolve the Dispute. The Senior Executives shall endeavor to resolve the Dispute through negotiation. If a Dispute is not resolved during Senior Executive negotiation within sixty (60) days, either Party may refer such Dispute to final and binding arbitration by sending written notice of such election to the other Party clearly marked "Arbitration Demand," whereupon such Dispute shall be arbitrated in accordance with this Section.

16.2. Arbitration Procedures. Any arbitration shall be conducted under the then-current expedited procedures applicable to the then-current Commercial Arbitration Rules of the AAA in accordance with this Section 16.2. The arbitration of any Dispute shall be kept confidential and shall be filed with the office of the AAA located in Wilmington, Delaware, or such other AAA office as the Parties may agree. The arbitration shall be conducted by three arbitrators, one appointed by each of Battelle and Discovery and the third selected by the first two appointed arbitrators. Each arbitrator shall be a person with relevant experience in the medical device development field. Battelle and Discovery must make their respective arbitrator appointments within ten (10) business days of receipt of an Arbitration Demand. Such appointed arbitrators shall select the third arbitrator within ten (10) business days after the second arbitrator has been appointed. Battelle and Discovery shall instruct such arbitrators to render a determination of any such Dispute within sixty (60) days after the appointment of the third arbitrator. All Disputes shall be resolved by submission of documents unless the arbitration panel determines that an oral hearing is necessary. The decision of the arbitrators with respect to any Dispute shall be in writing and state the findings, facts and conclusions of law upon which the decision is based. Any such decision and award rendered by the arbitrators shall be final and binding upon the Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. Each Party submits itself to the jurisdiction of any such court for the entry and enforcement to judgment with respect to the decision of the arbitrators hereunder. The arbitrators shall have the power to grant all legal and equitable remedies except specific performance and award compensatory damages provided by applicable law, but shall not have the power or authority to award punitive damages. No Party shall seek punitive damages or specific performance in relation to any matter relating to this Agreement in any other forum, provided that the foregoing does not preclude suits or limit damages associated with equitable relief related to a breach of confidentiality obligations under this Agreement or the CDA. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrators shall be equally shared between Battelle and Discovery unless the arbitrators assess all or any part of the arbitration expenses of a Party (including reasonable attorneys' fees) as part of their award against the other Party.

17. Applicable Law

This Agreement shall be governed by and construed in accordance with the laws of and enforced within the jurisdiction of the State of Delaware without regard to the principles of conflict of laws.

18. Survival

Sections 3, 4, 5, 7, 8, 9, and 12 through 19 of this Agreement shall survive the termination or expiration of this Agreement.

19. Miscellaneous

This Agreement may not be assigned in whole or in part without the prior written approval of both parties. Notwithstanding the foregoing, without the prior written approval of Battelle, Discovery may assign or otherwise transfer (including by operation of law) this Agreement in connection with a corporate transaction, including, without limitation, merger, combination, sale of stock, sale of assets, change of control, or other similar transaction, provided that the assignee assumes all of the obligations under this Agreement; however, no such assignment shall be made to an assignee if the assignee is on the Excluded Parties List (https://www.epls.gov/) or subject to an Executive Order (http://www.whitehouse.gov/briefing-room/presidential-actions/executive-orders) prohibiting transactions with the assignee. In any event, however, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by and against the successors, assigns, and transferees of the parties. If any part of this Agreement shall be held invalid or unenforceable, such invalidity and unenforceability shall not affect any other part of this Agreement. Captions used as headings in this Agreement are for convenience only and are not to be construed as a substantive part of this Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representative as of the Effective Date.

DISCOVERY LABORATORIES, INC.	**BATTELLE MEMORIAL INSTITUTE** **Corporate Operations**
By /s/ Mary B. Templeton	By /s/ Laura E. Fillman
Name Mary B. Templeton	Name Laura E. Fillman
Title Senior Vice President, General Counsel	Title Contracting Officer
Date June 22, 2012	Date June 22, 2012

Exhibit A

Invoicing Instructions

Battelle Memorial Institute
Corporate Operations
Proposal/Agreement No. OPP106184

Invoicing Instructions

Invoice(s) should be sent to the attention of:

(Name)

(Address)

(Reference: Purchase Order Number, OPP106184)

(Phone Number)

If additional invoices are required, please provide the following information:

Name	Address	Number of Invoices	Other

Please complete this form and return with the signed Agreement

Exhibit B

[***]

Exhibit 31.1

CERTIFICATIONS

I, W. Thomas Amick, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2012

/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: August 14, 2012

/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 June 30, 2012 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.
Date: August 14, 2012

/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.