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 March 31, 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 May 4, 2012, 43,371,562 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

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PART II - OTHER INFORMATION

Unless the context otherwise requires, all references to "we," "us," "our," and the "Company" include Discovery Laboratories, Inc., and its wholly owned, presently inact 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; the timing and expectations with respect to the planned 2012 commercial introduction of our drug and device products; the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our KL4 surfactant-based pipeline and our capillary aerosol generator (CAG) and ventilator circuit / patient interface connectors for delivery of aerosolized medications, including planning for and timing of any clinical trials and potential development milestones; the development of financial, clinical, manufacturing and distribution plans related to the potential commercialization of our products, if approved; and plans regarding potential strategic alliances and other collaborative arrangements with pharmaceutical companies and others to develop, manufacture and market our products.

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

- the risk that, if we 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 lack of marketing and distribution capabilities, which we will have to develop internally and secure through third-party strategic alliances and/or marketing alliances and/or distribution arrangements, that could require us to give up rights to our drug products, 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 SURFAXIN LS™ and AEROSURF®, 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 devices and novel ventilator circuit / patient interface connectors, for commercialization of our approved products and for preclinical and clinical studies of our product candidates;

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

- the risk that we, our contract manufacturers or any of our third-party suppliers may encounter problems or delays in manufacturing drug product substances, our drug products, 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 the 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: SURFAXIN LS (our lyophilized (freeze-dried) dosage form of SURFAXIN), and AEROSURF (our initial aerosolized KL_4 surfactant using our CAG technology); and (ii) AFECTAIR, a series of our novel ventilator circuit / patient interface connectors that we plan to introduce commercially in the fourth quarter of 2012;

- 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 involve time-consuming and expensive preclinical studies and other efforts, and potentially multiple clinical trials, which may be subject to potentially significant delays or regulatory holds or fail, and which must be conducted using sophisticated and extensive analytical methodologies 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 maintain 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®, 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) and the at-the-market (ATM) Program may be unavailable 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)

	March 31, 2012 (Unaudited)	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 54,802	$ 10,189
Prepaid expenses and other current assets	393	442
Total Current Assets	55,195	10,631
Property and equipment, net	2,143	2,293
Restricted cash	400	400
Total Assets	$ 57,738	$ 13,324
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,339	$ 1,111
Accrued expenses	2,887	2,972
Common stock warrant liability	10,304	6,996
Equipment loans and capitalized leases, current portion	67	68
Total Current Liabilities	14,597	11,147
Equipment loans and capitalized leases, non-current portion	205	224
Other liabilities	703	689
Total Liabilities	15,505	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; 43,382 and 24,603 shares issued, 43,361 and 24,582 shares outstanding respectively, at March 31, 2012 and December 31, 2011	43	25
Additional paid-in capital	452,680	401,713
Accumulated deficit	(407,436)	(397,420)
Treasury stock (at cost); 21 shares at March 31, 2012 and December 31, 2011	(3,054)	(3,054)
Total Stockholders' Equity	42,233	1,264
Total Liabilities & Stockholders' Equity	$ 57,738	$ 13,324

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

(in thousands, except per share data)

	Three Months Ended March 31,	
	2012	**2011**
Grant Revenue	$ –	$ 381
Expenses:		
Research and development	4,533	4,620
General and administrative	2,047	1,820
Total expenses	6,580	6,440
Operating loss	(6,580)	(6,059)
Change in fair value of common stock warrant liability	(3,434)	2,228
Other income / (expense):		
Interest and other income	2	4
Interest and other expense	(4)	(10)
Other income / (expense), net	(2)	(6)
Net loss	$ (10,016)	$ (3,837)
Net loss per common share – Basic and diluted	$ (0.37)	$ (0.21)
Weighted average number of common share outstanding – basic and diluted	27,162	18,114

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

(in thousands)

	Three Months Ended March 31,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (10,016)	$ (3,837)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	288	324
Stock-based compensation and 401(k) match	542	316
Fair value adjustment of common stock warrants	3,434	(2,228)
Loss / (gain) on sale of equipment	-	9
Changes in:		
Prepaid expenses and other current assets	49	(4)
Accounts payable	228	188
Accrued expenses	(85)	79
Other assets	-	5
Other liabilities and accrued interest	14	79
Net cash used in operating activities	(5,546)	(5,069)
Cash flows from investing activities:		
Purchase of property and equipment	(138)	(25)
Net cash used in investing activities	(138)	(25)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	43,604	22,583
Proceeds from exercise of common stock warrants	6,713	–
Repayment of equipment loans and capital lease obligations	(20)	(37)
Net cash provided by financing activities	50,297	22,546
Net increase in cash and cash equivalents	44,613	17,452
Cash and cash equivalents – beginning of period	10,189	10,211
Cash and cash equivalents – end of period	$ 54,802	$ 27,663
Supplementary disclosure of cash flows information:		
Interest paid	$ 4	$ 6

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 novel 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.

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.

Our strategy is initially to focus on the development of our KL_4 surfactant and aerosol technologies to improve the management of 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, beginning with SURFAXIN and, if approved, SURFAXIN LS™ and AEROSURF®, 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.

SURFAXIN LS is our lyophilized (freeze-dried) dosage form of SURFAXIN that is stored as a powder and resuspended to liquid form prior to use. We are developing 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 implementing a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States and other major markets worldwide. 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. Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may result in serious respiratory conditions and complications. As a consequence, neonatologists will not treat infants who could benefit from surfactant therapy unless the potential benefits of surfactant therapy outweigh the risks associated with such invasive administration procedures. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method. For this reason, 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 are currently not treated.

AFECTAIR, a series of disposable ventilator circuit / patient interface connectors, was initially developed for use 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. We initially developed a ventilator circuit / patient interface connector to be used with our CAG in the NICU. To benefit all critical care patients who require inhaled therapies and who are receiving ventilatory support, we are developing AFECTAIR devices in different sizes for use in NICUs, pediatric intensive care units (PICUs) and adult intensive care units (ICUs), and to be compatible with a variety of aerosol generating devices. In February 2012, we successfully registered our initial 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 believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients. We are implementing a regulatory and manufacturing plan that, if successful, is intended to result in the commercial introduction of the initial AFECTAIR device for use in the NICU in the United States and the European Union in the fourth quarter of 2012, and a second AFECTAIR device, AFECTAIR® DUO, in mid-2013.

We are preparing for the commercial introductions, beginning in late 2012, of SURFAXIN in the United States, and AFECTAIR in the United States, the European Union and thereafter in other markets worldwide. To accomplish our objectives, in the United States, we plan to build our own, in-house, specialty respiratory critical care commercial and medical affairs organization that will specialize in neonatal indications, beginning with SURFAXIN. We also expect that our commercial and medical affairs organization will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN to efficiently support the introductions of SURFAXIN LS and AEROSURF, if approved. In the future, our in-house organization may also work in a coordinated manner with a network of third-party distributors to support commercial distribution of the AFECTAIR devices.

In major markets outside the United States, 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, early 2013 is to secure one or more strategic alliances and/or collaboration arrangements potentially to share research and development expenses for our SURFAXIN LS and AEROSURF 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 approval of SURFAXIN by the FDA. 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), capital equipment and debt facilities, and strategic alliances.

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

As of March 31, 2012, we had cash and cash equivalents of $54.8 million. As of March 31, 2012, (i) holders of the 15-month warrants issued in February 2011 have exercised warrants to purchase 2,233,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million; and (ii) holders of the five-year warrants we issued in February 2011 (February 2011 five-year warrants) have exercised warrants to purchase 46,250 shares of our common stock at an exercise price of $3.20 per share, resulting in proceeds to us of $148,000. In addition, 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. As a result of that offering, we issued an aggregate 350,374 shares of 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. On March 21, 2012, we completed a public offering of 16,071,429 shares of common stock for net proceeds to us (after underwriter fees and anticipated expenses) of approximately $42.1 million.

As of March 31, 2012, of the 100 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, we had available for issuance, and not otherwise reserved for future issuance, approximately 40.0 million shares of common stock.

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:

Exercise of outstanding warrants:

- In connection with our February 2011 public offering, we issued 15-month warrants to purchase five million shares of our common stock at an exercise price of $2.94 per share (15-month warrants) of which 2,233,000 warrants have been exercised through March 31, 2012. If the market price of our common stock should exceed $2.94 at any time prior to May 22, 2012 (the expiration date of these warrants), and if the holders determine (in their discretion) to exercise the remaining outstanding 15-month warrants and we have an effective registration statement covering the warrant shares, we potentially could raise up to an additional $8.1 million.
- Also in connection with the February 2011 public offering, we issued the February 2011 five-year warrants to purchase five million shares of our common stock at an exercise price of $3.20 per share, of which 46,250 have been exercised through March 31, 2012. These warrants also 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. As a result of the March 2012 public offering, the exercise price of these warrants has been adjusted downward to $2.80 per share. Thus, if the market price of our common stock should exceed $2.80 at any time prior to February 2016 (the expiration date of these warrants), and if the holders determine (in their discretion) to exercise the remaining outstanding February 2011 five-year warrants, and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants, we potentially could raise up to an additional $13.9 million.

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 SURFAXIN LS and AEROSURF 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 could allow us, at 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 May 4, 2012 ($2.71) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.7 million.
- In December 2011, we established an “at-the-market” program (ATM Program), which allows us, at our discretion and at such times that we may choose, to sell up to a maximum of $15 million of shares of common stock. As of March 31, 2012, $13.4 million remained available under the ATM Program.

- We have agreed in connection with our March 2012 public offering that we will not issue or sell (with certain limited exceptions) securities, including under our CEFF and ATM Program, for a period of 90 days ending in June 2012.

There can be no assurance 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; that we will be successful in concluding any strategic alliance, collaboration or other financing transaction; 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; that we will issue any shares pursuant to the ATM Program, or that the entire amount provided under the ATM Program will be realized prior the expiration or earlier termination of the ATM Program; or that we will undertake any financings or similar transactions, on favorable terms or otherwise.

We believe, if we are successful in implementing our strategic business plan, that the anticipated net revenues from the sale of SURFAXIN and AFECTAIR, when combined with the other sources of anticipated capital outlined above, including from potential strategic alliances and collaboration arrangements to support the SURFAXIN LS and AEROSURF development programs, potentially could be sufficient to support our future operations. In that event, we would nevertheless continue to consider financings and similar transactions that would strengthen our financial condition and build value for our stockholders.

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; 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 SURFAXIN LS and AEROSURF 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 SURFAXIN LS and AEROSURF, and if approved, commercialization of SURFAXIN LS and AEROSURF 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 months ended March 31, 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. Based on our assessment, there was no inventory qualifying for capitalization as of March 31, 2012. 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.

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 quarter ended March 31, 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 March 31, 2012 and 2011, 13.2 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.

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). 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 per share, which expired unexercised in April 2012. In connection with this offering, we also agreed not to issue or sell (with certain limited exceptions) securities, including under our ATM Program and CEFF, for a period of 90 days ending June 14, 2012.

At-the-Market (ATM) Program

We have an ATM Program with Lazard Capital Markets LLC (Lazard), under which Lazard, as our exclusive agent and 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 are not required to sell any shares at any time during the term of the ATM Program. We have 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 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.

As of March 31, 2012, $13.4 million remained available under the ATM Program.

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 in our 2011 Form 10-K, for a detailed description of our CEFF.

As of March 31, 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 May 4, 2012 ($2.71) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.7 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 March 31, 2012 and December 31, 2011:

	Fair Value March 31, 2012	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Money Market	$ 47,377	$ 47,377	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 47,777	$ 47,777	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 10,304	$ –	$ –	$ 10,304

	Fair Value December 31, 2011	Fair value measurement using 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 three months ended March 31, 2012:

(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]	(126)
Change in fair value of common stock warrant liability	3,434
Balance at March 31, 2012	$ 10,304

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

The significant unobservable inputs used in the fair value measurement of the May 2009 and February 2010 common stock warrant 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 the closing price of our common stock on the measurement date, and 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	March 31, 2012	December 31, 2011
Historical Volatility	89% - 113%	98% - 116%
Expected Term (in years)	2.1 - 3.9	2.4 - 4.2
Risk-free interest rate	0.33% - 0.78%	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 March 31, 2012 are as follows:

Issuance Date	Number of Warrant Shares Issuable	Exercise Price	Warrant Expiration Date	Fair Value of Warrants (in thousands)	
				Issuance Date	March 31, 2012
5/13/2009	466,667	$ 17.25	5/13/2014	$ 3,360	$ 119
2/23/2010	916,669	12.75	2/23/2015	5,701	896
2/22/2011	4,953,750	2.80	2/22/2016	8,012	9,289

During the quarter ended March 31, 2012, holders of the February 2011 five-year warrants exercised warrants to purchase 46,250 shares of common stock for total proceeds of $148,000. In addition, as a result of our March 2012 registered public offering, the exercise price of the February 2011 five-year warrants was adjusted downward from $3.20 per share to $2.80 per share, in accordance with the anti-dilution provisions of the warrant.

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.

	March 31,	
	2012	**2011**
Weighted average expected volatility	113%	112%
Weighted average expected term	4.8 years	4.9 years
Weighted average risk-free interest rate	1.08%	1.47%
Expected dividends	–	–

The total employee stock-based compensation for the three ended March 31, 2012 and 2011 was as follows:

(in thousands)	Three Months Ended March 31,	
	2012	**2011**
Research and development	$ 120	$ 63
General and administrative	278	118
Total	$ 398	$ 181

As of March 31, 2012, there was $2.3 million of total unrecognized compensation cost related to non-vested 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 for stock options.

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 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) appearing elsewhere herein.

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 novel 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.

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.

Our strategy is initially to focus on the development of our KL_4 surfactant and aerosol technologies to improve the management of 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, beginning with SURFAXIN and, if approved, SURFAXIN LS™ and AEROSURF®, 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.

SURFAXIN LS is our lyophilized (freeze-dried) dosage form of SURFAXIN that is stored as a powder and resuspended to liquid form prior to use. We are developing 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 implementing a regulatory plan intended to gain marketing authorization for SURFAXIN LS in the United States and other major markets worldwide. 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. Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may result in serious respiratory conditions and complications. As a consequence, neonatologists will not treat infants who could benefit from surfactant therapy unless the potential benefits of surfactant therapy outweigh the risks associated with such invasive administration procedures. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method. For this reason, 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 are currently not treated.

AFECTAIR, a series of disposable ventilator circuit / patient interface connectors, was initially developed for use 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. We initially developed a ventilator circuit / patient interface connector to be used with our CAG in the NICU. To benefit all critical care patients who require inhaled therapies and who are receiving ventilatory support, we are developing AFECTAIR devices in different sizes for use in NICUs, pediatric intensive care units (PICUs) and adult intensive care units (ICUs), and to be compatible with a variety of aerosol generating devices. In February 2012, we successfully registered our initial 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 believe that AFECTAIR has the potential to become a new standard of care for the delivery of inhaled therapies to critical care patients. We are implementing a regulatory and manufacturing plan that, if successful, is intended to result in the commercial introduction of the initial AFECTAIR device for use in the NICU in the United States and the European Union in the fourth quarter of 2012, and a second AFECTAIR device, AFECTAIR® DUO, in mid-2013.

We are preparing for the commercial introductions, beginning in late 2012, of SURFAXIN in the United States, and AFECTAIR in the United States, the European Union and thereafter in other markets worldwide. To accomplish our objectives, in the United States, we plan to build our own, in-house, specialty respiratory critical care commercial and medical affairs organization that will specialize in neonatal indications, beginning with SURFAXIN. We also expect that our commercial and medical affairs organization will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN to efficiently support the introductions of SURFAXIN LS and AEROSURF, if approved. In the future, our in-house organization may also work in a coordinated manner with a network of third-party distributors to support commercial distribution of the AFECTAIR devices.

In major markets outside the United States, 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, early 2013 is to secure one or more strategic alliances and/or collaboration arrangements potentially to share research and development expenses for our SURFAXIN LS and AEROSURF 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 approval of SURFAXIN by the FDA. 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 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), 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 post-approval activities in preparation for the commercial introduction of SURFAXIN, including building a commercial and medical affairs organization. Because SURFAXIN is a hospital-based product, we will work with hospitals that have NICUs to include SURFAXIN on each such hospital's formulary, which is 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. To facilitate proper preparation and administration of SURFAXIN, 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. We have registered the WARMING CRADLE with the FDA as a Class I, exempt medical device. We are also working with hospitals to clear our WARMING CRADLE at each of these hospitals to make WARMING CRADLEs available for use.

- AFECTAIR

  AFECTAIR is a series of disposable ventilator circuit / patient interface connectors and related componentry that introduces inhaled therapies directly to the patient interface and minimizes the number of connections in the regulatory circuit without compromising ventilatory support. We have registered our initial AFECTAIR device in the United States and plan to introduce this neonatal-sized device in the fourth quarter of 2012. We expect that our commercial and medical affairs organization will support the planned commercial introduction of AFECTAIR in the United States. We originally planned to enter into arrangements with third-party distributors to support the introduction of AFECTAIR; however, because we generally expect to market the AFECTAIR neonatal-sized device to the same hospitals to which we plan to market SURFAXIN, we are currently assessing various methods of distribution and will determine 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.

- SURFAXIN LS and AEROSURF Development Programs

  We are continuing our development activities for both SURFAXIN LS and AEROSURF development programs. In 2012, we plan to advance the technology transfer of our SURFAXIN LS lyophilized manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in lyophilized formulations and we expect to have further interactions with the FDA regarding the SURFAXIN LS development program as well as obtain regulatory guidance with respect to our planned development program in Europe. To advance our AEROSURF program, we continue our efforts to optimize the design of our capillary aerosolization device with our own engineering staff and third-party medical device experts. As development work proceeds, we plan to seek regulatory guidance for AEROSURF for the United States and Europe. We intend to initiate our clinical programs for each of these product candidates after we have developed a final development strategy and after we have secured the necessary strategic alliances and/or capital. For a detailed discussion of these development programs, *see*, "Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – SURFAXIN LS™ – Lyophilized SURFAXIN® for RDS in Premature Infants," and "– AEROSURF® for RDS in Premature Infants," in our 2011 Form 10-K.

CRITICAL ACCOUNTING POLICIES

Other than as noted below, 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. Based on our assessment, there was no inventory qualifying for capitalization as of March 31, 2012. 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.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the three months ended March 31, 2012 and 2011 was $10.0 million and $3.8 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 $3.4 million for the three months ended March 31, 2012 and non-cash income of $2.2 million for the three months ended March 31, 2011.

The operating loss for the three months ended March 31, 2012 and 2011 was $6.6 million and $6.1 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), in accordance with terms of the J&J licensing agreement, upon FDA approval of SURFAXIN®; (ii) non-cash items related to depreciation and stock-based compensation of $0.7 million and $0.5 million for 2012 and 2011, respectively; and (iii) in the first quarter of 2011, $0.4 million of grant revenue. Excluding the one-time, non-recurring items noted above and non-cash items related to depreciation and stock-based compensation, the operating loss was $5.4 million and $5.9 million for 2012 and 2011, respectively.

Grant Revenue

We did not recognize any revenues for the three months ended March 31, 2012. For the three months ended March 31, 2011, we recognized grant revenue of $0.4 million, for funds received and expended under a Fast Track Small Business Innovation Research Grant (SBIR) from the National Institutes of Health to support the development of aerosolized KL4 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 KL4 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 months ended March 31, 2012 and 2011 are as follows:

(Dollars in thousands)	Three Months Ended March 31,	
Research and Development Expenses[1]	**2012**	**2011**
Product development and manufacturing	$ 3,103	$ 3,046
Medical and regulatory operations	823	905
Direct preclinical and clinical programs	607	669
Total Research and Development Expenses	$ 4,533	$ 4,620

[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 for the three months ended March 31, 2012 and 2011.

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.

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) medical affairs activities to provide scientific and medical education support in connection with our KL_4 surfactant and aerosol delivery product candidates. 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.

With respect to our planned commercial introduction of SURFAXIN and AFECTAIR in late 2012, we expect to incur expenses at an annual rate of approximately $12-$13 million, which primarily represents investment in 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. We anticipate that our medical affairs personnel will provide medical education support for both SURFAXIN and AFECTAIR, as both products may be of interest to many of the same medical practitioners and involve many of the same medical congresses, many of the same medical journals and publications, and many of the same hospitals. We expect that this anticipated synergy will result in certain economies for each of these products.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) activities related to responding to 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 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 March 31, 2012 includes a $0.5 million charge related to a milestone payment that became payable to J&J, in accordance with terms of the J&J licensing agreement, upon FDA approval of SURFAXIN. Direct preclinical and clinical programs expense for the three months ended March 31, 2011 includes $0.6 million of costs associated with activities related to responding 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 SURFAXIN LS and AEROSURF development programs. To prepare for initiation of our SURFAXIN LS and AEROSURF clinical trials, we plan to obtain regulatory guidance to understand the regulatory requirements regarding 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

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete individual projects in development are not reasonably estimable. With every phase of a development project, there are significant unknowns that may significantly affect cost projections and timelines. As a result of the number and nature of these factors, many of which are outside our control, the success, timing of completion and ultimate cost, of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. Certain of the risks and uncertainties affecting our ability to estimate projections and timelines are discussed in our 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, SURFAXIN LS and AEROSURF, and (ii) developing our proprietary ventilator circuit / patient interface connectors to potentially introduce a series of AFECTAIR devices in the U.S. and European markets. 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 Pipeline Programs Update described in "– Overview – Business and Pipeline Programs Update," the following updates since the filing of our Form 10-K relate to our research and development programs:

- With respect to SURFAXIN drug product, data from a new pharmacoeconomic analysis was 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 the AFECTAIR series of devices, data from performance studies conducted using the AFECTAIR neonatal-size 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-size device as compared to standard of care. Albuterol was aerosolized with a jet nebulizer and delivered using both the AFECTAIR neonatal-size 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-size device compared with standard of care. The study concluded that the AFECTAIR neonatal-size 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-size 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. We anticipate that further studies will be conducted and potentially presented at congresses in 2012 and 2013.

General and Administrative Expenses

General and administrative expenses consist primarily of the costs of executive management, business and commercial development, finance and accounting, intellectual property and legal, human resources, information technology, facility and other administrative costs.

General and administrative expenses were $2.0 million and $1.8 million for the three months ended March 31, 2012 and 2011, respectively. Included in general and administrative expenses were non-cash charges associated with stock-based compensation and depreciation of $0.3 million and $0.2 million, respectively. Excluding the stock-based compensation and depreciation, general and administrative expenses increased $0.1 million for the three months ended March 31, 2012 compared to the same period in 2011.

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 and information technologies. With these investments, we believe that our general and administrative resources will be sufficient to support our business operations.

With respect to our planned commercial introduction of SURFAXIN and AFECTAIR in late 2012, we expect to incur expenses at an annual rate of approximately $12-$13 million, which primarily represents investment in marketing, field-based sales and medical affairs capabilities. Of this amount, the portion attributed to marketing and field based sales will be charged to general and administrative expenses. *See also*, "–Results of Operations – Research and Development Expenses – 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*, "Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations," in our 2011 Form 10-K.

Change in Fair Value of Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in Accounting Standards Codification (ASC) Topic 815 – "Derivatives and Hedging — Contracts in Entity's Own Equity," as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. The registered warrants that we issued in May 2009 and February 2010 are classified as derivative liabilities and valued using the Black-Scholes pricing model. The five-year registered warrants that we issued in February 2011 (February 2011 five-year warrants) are classified as derivative liabilities and valued using a trinomial pricing model. Valuations of these warrants occur at the date of initial issuance and each subsequent balance sheet date. The change in the fair value of the warrants is included in the consolidated statement of operations as "Change in the fair value of common stock warrant liability." *See*, Notes 5 and 6 to our Consolidated Financial Statements in this Quarterly Report on Form 10-Q.

The change in the fair value of common stock warrant liability resulted in expense of $3.4 million and income of $2.2 million for the three months ended March 31, 2012 and 2011, respectively, due primarily to changes in our common stock share price during the periods.

Other Income and (Expense)

Other income and (expense) for the three months ended March 31, 2012 and 2011 is as follows:

(in thousands)	Three Months Ended March 31, 2012	2011
Interest income	$ 2	$ 4
Interest expense	(4)	(6)
Other income / (expense)	–	(4)
Other income / (expense), net	$ (2)	$ (6)

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

Interest expense for the three months ended March 31, 2012 and 2011 consists of interest on our equipment financing facilities.

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), capital equipment and debt facilities, and strategic alliances.

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

As of March 31, 2012, we had cash and cash equivalents of $54.8 million. As of March 31, 2012, (i) holders of the 15-month warrants issued in February 2011 have exercised warrants to purchase 2,233,000 shares of our common stock at an exercise price of $2.94 per share, resulting in proceeds to us of $6.6 million; and (ii) holders of the February 2011 five-year warrants have exercised warrants to purchase 46,250 shares of our common stock at an exercise price of $3.20 per share, resulting in proceeds to us of $148,000. In addition, 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. As a result of that offering, we issued an aggregate 350,374 shares of 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. On March 21, 2012, we completed a public offering of 16,071,429 shares of common stock for net proceeds to us (after underwriter fees and anticipated expenses) of approximately $42.1 million. In connection with this offering, we 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 per share, 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.

As of March 31, 2012, of the 100 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, we had available for issuance, and not otherwise reserved for future issuance, approximately 40.0 million shares of common stock.

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:

Exercise of outstanding warrants:

- In connection with our February 2011 public offering, we issued 15-month warrants to purchase five million shares of our common stock at an exercise price of $2.94 per share (15-month warrants) of which 2,233,000 warrants have been exercised through March 31, 2012. If the market price of our common stock should exceed $2.94 at any time prior to May 22, 2012 (the expiration date of these warrants), and if the holders determine (in their discretion) to exercise the remaining outstanding 15-month warrants and we have an effective registration statement covering the warrant shares, we potentially could raise up to an additional $8.1 million.
- Also in connection with the February 2011 public offering, we issued the February 2011 five-year warrants to purchase five million shares of our common stock at an exercise price of $3.20 per share, of which 46,250 have been exercised through March 31, 2012. These warrants also 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. As a result of the March 2012 public offering, the exercise price of these warrants has been adjusted downward to $2.80 per share. Thus, if the market price of our common stock should exceed $2.80 at any time prior to February 2016 (the expiration date of these warrants), and if the holders determine (in their discretion) to exercise the remaining outstanding February 2011 five-year warrants and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants, we potentially could raise up to an additional $13.9 million.

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 SURFAXIN LS and AEROSURF and, if approved, the introduction of these products in 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 could allow us, at 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 May 4, 2012 ($2.71) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.7 million.

- In December 2011, we established an "at-the-market" program (ATM Program), which allows us, at our discretion and at such times that we may choose, to sell up to a maximum of $15 million of shares of common stock. As of March 31, 2012, $13.4 million remained available under the ATM Program.
- We have agreed in connection with our March 2012 public offering that we will not issue or sell (with certain limited exceptions) securities, including under our CEFF and ATM Program, for a period of 90 days ending in June 2012.

There can be no assurance 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; that we will be successful in concluding any strategic alliance, collaboration or other financing transaction; 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; that we will issue any shares pursuant to the ATM Program, or that the entire amount provided under the ATM Program will be realized prior the expiration or earlier termination of the ATM Program; or that we will undertake any financings or similar transactions, on favorable terms or otherwise.

We believe, if we are successful in implementing our strategic business plan, that the anticipated net revenues from the sales of SURFAXIN and AFECTAIR, when combined with the other sources of anticipated capital outlined above, including from potential strategic alliances and collaboration arrangements to support the SURFAXIN LS and AEROSURF development programs, potentially could be sufficient to support our future operations. In that event, we would nevertheless continue to consider financings and similar transactions that would strengthen our financial condition and build value for our stockholders.

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; 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 SURFAXIN LS and AEROSURF 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 SURFAXIN LS and AEROSURF, and if approved, commercialization of SURFAXIN LS and AEROSURF 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 March 31, 2012, we had cash and cash equivalents of $54.8 million compared to $10.2 million as of December 31, 2011. Cash outflows before financings for the three months ended March 31, 2012 consisted of $5.5 million used for ongoing operating activities, $138,000 for purchases of property and equipment, and $20,000 used for debt service. Through March 31, 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 financings under our ATM program.

Cash Flows From Operating Activities

Net cash used in operating activities was $5.5 million and $5.1 million for the three months ended March 31, 2012 and 2011, respectively.

Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items associated with the change in fair value of common stock warrants (expense of $3.4 million in 2012 and income of $2.2 million in 2011), stock-based compensation and depreciation expense ($0.8 million and $0.6 million in 2012 and 2011, respectively), and changes in working capital.

Cash Flows From Investing Activities

Net cash used in investing activities represents purchases of property and equipment of $138,000 and $25,000 for the three months ended March 31, 2012 and 2011, respectively.

Cash Flows from Financing Activities

Net cash provided by financing activities was $50.3 million and $22.5 million for the three months ended March 31, 2012 and 2011, respectively, summarized as follows:

(In millions)	Three Months Ended March 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 (ATM) Program

In December 2011, we entered into a Sales Agency Agreement (Agency Agreement) with Lazard Capital Markets LLC (Lazard), under which Lazard, as our exclusive agent and 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. We are not required to sell any Shares at any time during the term of the 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 has a two year term, subject to earlier termination as provided in the Agency Agreement We have 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.

As of March 31, 2012, $13.4 million remained available under the ATM Program.

Committed Equity Financing Facility (CEFF)

As of March 31, 2012, we had a Committed Equity Financing Facility (CEFF) dated June 11, 2010 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 March 31, 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 May 4, 2012 ($2.71) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $2.7 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 March 31, 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

As of March 31, 2012, approximately $0.3 million was outstanding ($67,000 classified as current liabilities and $205,000 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 our SURFAXIN drug product, we had not complied with the Jobs Covenant by the end of 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 March 31, 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.

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;
- SURFAXIN's and AFECTAIR's perceived advantages 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);

- perception of our products and devices by members of the healthcare community, including physicians;
- the acceptance of AFECTAIR devices as the standard of care for delivery of inhaled therapies for patients requiring ventilatory support;
- 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 SURFAXIN's labeling;
- 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 ourselves or through third-party manufacturers, and our ability to meet commercial demand for SURFAXIN.

We cannot predict the extent to which SURFAXIN will be utilized in the rest of the world or whether physicians, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize SURFAXIN, AFECTAIR and other related 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 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 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 failure 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, they 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. 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 and products to the formulary, 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 P&T committees 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 dry block-warming device called a WARMING CRADLE® 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 the WARMING CRADLE on the hospital's list of approved devices.

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 a second AFECTAIR device. 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 we or our partners do not meet our respective obligations. In addition, our partners may provide certain services for us, such as 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 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 collaborators may be developing or marketing a variety of products, some with other partners. Collaborators with whom we enter into distribution agreements my sell and market products that compete with ours. Our collaborators 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 a collaboration arrangement with us. Our collaborators may also develop products that are similar to or compete with products they are developing in collaboration with us. If our collaborators pursue these 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.

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 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 the target patient population to try new products and of physicians to prescribe 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
- the effectiveness of our marketing strategy and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

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. 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 adverse event reporting system, 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 not only with the requirements of the FDA and international regulators, but will also become subject to various federal, state and international laws regulating healthcare "fraud and abuse." These laws govern such activities as our relationships with healthcare providers, the sale and marketing or our products, and pricing of prescription drug products and medical devices. These laws include anti-kickback laws and false claims laws. 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 third party payers (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. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Many pharmaceutical 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 can include significant and costly burdens. Private individuals may bring similar actions. There are also an increasing number of state laws that require manufacturers to make reports to those states on 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.

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.

We are developing compliance programs, including policies, training and various forms of monitoring, designed to address these risks. However, these programs and policies may not always protect us from conduct by individual employees, well meaning or otherwise, that violate these laws. 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 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.

In particular, we filed with the FDA an NDA for SURFAXIN for the prevention of RDS in premature infants. We received the 2009 Complete Response Letter, which raised various questions concerning our fetal rabbit biological activity test (BAT), an important release and stability test for SURFAXIN.. Following a number of exchanges with the FDA, we conducted a comprehensive preclinical program that consisted of a series of prospectively-designed, side-by-side preclinical studies employing our optimized BAT and the well-established preterm lamb model of RDS. These time-consuming studies were intended to demonstrate comparability of drug product used in the Phase 3 clinical program with SURFAXIN drug product to be manufactured for commercial use, and to gain the FDA's agreement on final acceptance criteria, with respect to biological activity as assessed by the BAT, for release and ongoing stability of SURFAXIN drug product. *See*, "Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS) – SURFAXIN for the Prevention of RDS in Premature Infants at High Risk for RDS," in our 2011 Form 10-K.

To gain approval of SURFAXIN LS and AEROSURF, 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 SURFAXIN LS and AEROSURF 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. There can be no assurance that we will be successful in gaining regulatory approval for SURFAXIN LS and / or AEROSURF, if at all, within our expected time frame.

We plan to pursue clinical development and commercialization in the European Union and otherwise market and sell our products in 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 target 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 have completed our Phase 3 clinical trials for SURFAXIN for the prevention of RDS in premature infants and certain Phase 2 trials for other drug product candidates for other indications. If we successfully advance our other KL_4 surfactant development programs for SURFAXIN LS and AEROSURF for RDS through the initial preclinical phase of development, we plan to conduct, for AEROSURF, Phase 2 and, for SURFAXIN LS and AEROSURF, Phase 3 clinical trials, 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 SURFAXIN LS and AEROSURF, 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.

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 will need to hire additional qualified personnel to support (i) the commercialization of SURFAXIN and AFECTAIR, and (ii) the advancement of our SURFAXIN LS and AEROSURF development programs. In particular, over the next 12 months, we expect to hire approximately 60 new employees primarily in the areas of field based sales and marketing, medical affairs, regulatory affairs, and quality control and assurance. We expect that the hiring of such additional personnel will increase our annual expenditures by approximately $8.0 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 for these agreements, which expired on May 3, 2012. In addition, we had retention agreements with five other executive officers under which each officer is 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. Our industry generally seeks to attract and retain executive talent with compensation packages that include a significant equity component. 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. We plan in the future to seek stockholder approval for additional authorizations to support the use of equity incentives. However, there can be no assurance that our stockholders will approve such incentives and, even if our stockholders approve new equity incentives that we will be able to attract and retain key executive talent in the interim period.

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. If 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 approved, 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 three months ended March 31, 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 March 31, 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: May 15, 2012

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

Date: May 15, 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+	Product Development and Supply Agreement between Discovery and Lacey Manufacturing Company, a Division of Precision Engineered Products, LLC	Filed herewith
10.2*	Form of Employee Option Agreement under Discovery's 2011 Long-Term Incentive Plan	Filed herewith
10.3*	Form on Non-Employee Director Agreement under Discovery's 2011 Long-Term Incentive Plan	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. Annual Report on Form 10-K for the year ended December 31, 2011, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2011 and December 31, 2010, (ii) Statements of Operations for the years ended December 31, 2011 and December 31, 2010, (iii) Statements of Changes in Equity for the years ended December 31, 2011 and December 31, 2010, (iv) Statements of Cash Flows for the years ended December 31, 2011 and December 31, 2010, 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.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 10.1

Product Development and Supply Agreement

Between

Lacey Manufacturing Company,
a Division of Precision Engineered Products, LLC
1146 Barnum Avenue, Bridgeport, Connecticut 06610
(Also referred to as "**LACEY**")

and

Discovery Laboratories, Inc.
2600 Kelly Road
Warrington, Pennsylvania 18976

(Also referred to as "**DSCO**")

February 1, 2012

AGREEMENT

This Product Development and Supply Agreement ("**Agreement**") between Lacey Manufacturing Company, a Division of Precision Engineered Products, LLC ("**PEP**"), with offices at 1146 Barnum Avenue, Bridgeport, Connecticut 06610 ("**LACEY**") and Discovery Laboratories, Inc., with offices at 2600 Kelly Road, Warrington, Pennsylvania 18976 ("**DSCO**") is effective as of February 1, 2012 (the "**Effective Date**").

Background

LACEY is a full service, vertically integrated ISO 9001/2008, 13485/2003 Medical Certified Contract Manufacturer of finished assemblies, subassemblies and precision components that provides quality assurance, engineering, metal stamping, injection molding, and assembly services for the Medical Device, Commercial and Bearing Markets.

DSCO is a specialty biotechnology company focused on improving the standard of care for the treatment of respiratory diseases. **DSCO** is developing its proprietary (i) KL_4 surfactant technology, and (ii) drug delivery technologies, including its capillary aerosolization technology and novel ventilator circuit / patient interface connectors. In the second half of 2010, **DSCO** determined that there may be a commercial market for its ventilator circuit / patient interface connectors, if offered as stand-alone medical device products, and is planning to market two versions of the connectors under the trademarks AFECTAIR® and AFECTAIR® DUO (the "**AFECTAIR Devices**").

From and after November 24, 2010 ("**Initial Contact Date**"), **DSCO** and **LACEY** have engaged in discussions and activities (collectively, "**Preparatory Activities**") concerning the potential manufacture of the **AFECTAIR Devices**. **Preparatory Activities** have included, among other things, discussions concerning the **Design** of the **AFECTAIR Devices**, changes to the **Design** intended to improve **Manufacturing** efficiency and reliability, and development of drawings and **Specifications** intended to support **Manufacturing**. The **Parties** are entering into this **Agreement** to advance their activities to the **Manufacturing** phase.

Introduction

1. Purpose. This **Agreement** relates to the development and **Manufacture** of **AFECTAIR Devices**, as described in Appendix A (the "**Program**") and in accordance with the **Quality Agreement**, which will appended to this **Agreement** as Appendix B (the "**Quality Agreement**") prior to the initiation of commercial production, and any applicable **Purchase Order** issued under this **Agreement**.
2. Term. Subject to Section 30, this **Agreement** will remain effective for a period of three years from the date of the first production **Purchase Order** for **Manufacture** of commercially saleable **AFECTAIR Devices**, or four years from the Effective Date, whichever is shorter (the "**Term**"). The **Term** may be extended by written agreement of the **Parties**.
3. Definitions**.** If not otherwise defined in this **Agreement**, the terms presented in bold type shall have the meanings set forth in this Section 3. Unless otherwise indicated, references to Sections refer to Sections in this **Agreement** and references to Sections in the accompanying Appendices to this **Agreement** refer to each such Appendix, as applicable. Unless otherwise defined, the defined terms in this **Agreement** and the Appendices attached to this **Agreement** have the following meanings:

[***] Denotes Material is Subject to a Confidential Treatment Request

3.1. "AFECTAIR" is**DSCO**'s trademark registered in the **US** Patent and Trademark Office for a medical device intended to simplify delivery of aerosolized medication to patients requiring positive pressure ventilatory support as described in the International Patent Publication WO 2009/117422 and **US** Patent Application Serial Number 12/922981.

3.2. "AFECTAIR DUO" is **DSCO**'s trademark for a medical device combined with a delivery circuit as described in the International Patent Publication WO 2009/117422 and **US** Patent Application Serial Number 12/922981.

3.3. "**AFECTAIR Devices**" means either or both of the AFECTAIR and AFECTAIR DUO medical devices.

3.4. "**Affiliate**" shall mean any individual, firm, corporation or other legal entity that directly or indirectly controls, is controlled by, or is under common control with, a **Party**. As used in the preceding sentence, "control" means possession, whether direct or indirect, of the power to direct or cause the direction of the management and policies of such entity, whether pursuant to the ownership of voting securities, by contract or otherwise. For the purposes of this **Agreement**, **LACEY** and Precision Engineered Products, LLC are considered **Affiliates** with respect to each other.

3.5. "**Agreement**" means this Product Development and Supply Agreement, including the Appendixes, Schedules and Addendums attached hereto, and the **Quality Agreement,** and includes all **Purchase Orders** issued pursuant to this **Agreement**, as each may be amended from time to time.

3.6. "**Confidential Information**" has the meaning set forth in the Mutual Confidential Disclosure Agreement dated November 24, 2010, between **DSCO** and **LACEY**.

3.7. "**Days**" means business days, unless otherwise noted in a specific instance.

3.8. "**Design**" means activities related to design of **AFECTAIR Devices**, changes to the design and drawings, including without limitation, designing a device to be **Manufactured** to contain a single part or multiple parts.

3.9. "**DSCO Improvements**" has the meaning set forth in Section 7.2.2.

3.10. "**DSCO Representative**" means the individual(s) designated to receive notices related to the **Manufacturing** operations and regulatory developments. **DSCO** will notify **LACEY** of the name and address of its representative within five **Days** after the **Effective Date**.

3.11. "**Equipment**" has the meaning set forth in Section 5. 2 and Appendix A-2, as the same may be amended from time to time.

3.12. "**EU**" means the European Union and includes at a minimum the following countries: United Kingdom, Germany, France, Italy, and Spain.

3.13. "**FDA**" means U.S. Food and Drug Administration.

3.14. "**FDC Act**" means the Federal Food, Drug, and Cosmetic Act, as amended.

3.15. "**Good Manufacturing Practices**" or "**GMP**" means current good manufacturing practices, as specified in regulations promulgated from time to time by the **FDA** in its **Quality System Regulations,** and comparable regulations by other international Regulatory Authorities (e.g., EMA) for the manufacture and testing of pharmaceutical products.

3.16. "**Initial Contact Date**" has the meaning set forth in the Background to the **Agreement**.
3.17. "**Intellectual Property**" means all patents, patent applications, copyrights, trademarks, trade names, trade secrets, know-how, service marks, licenses and other intellectual property rights of a **Party**, that may be secured in any place under **Laws** now or hereafter in effect.
3.18. "**Invention**" means any new or improved apparatus, process, information, product, invention, discovery, idea, suggestion, material, data, equipment, design, circuit component, drawing, tooling, prototype, report, computer software, documentation or other **Intellectual Property** or know-how (whether or not patentable) discovered, produced, conceived, created or reduced to practice by either or both **Parties** (or their **Affiliates**, sublicensees, subcontractors, successors or assigns).
3.19. "**ISO 13485**" means the International Organization of Standardization's standard that represents the requirements for a comprehensive quality management system for the design and development, manufacture, installation and servicing of medical devices.
3.20. "**JOINT Improvements**" has the meaning set forth in Section 7.2.3.
3.21. "**Labeling**" means all labels and other written, printed, or graphic material affixed to or accompanying any **AFECTAIR Devices** or any containers of **AFECTAIR Devices** or wrappers accompanying such **AFECTAIR Devices** (e.g., instruction sheets, package inserts).
3.22. "**LACEY Improvements**" has the meaning set forth in Section 7.2.1.
3.23. "**LACEY Representative**" means the individual(s) designated to receive notices related to the **Manufacturing** operations and regulatory developments. **LACEY** will notify **DSCO** of the name and address of its representative within five (5) **Days** after the **Effective Date**.
3.24. "**Laws**" means all applicable laws, statutes, rules, regulations, ordinances, and pronouncements of law of any foreign, federal, state, or local government.
3.25. "**Manufacture**" and "**Manufacturing**" means the manufacturing, processing, holding, testing, **Labeling**, and packaging of **AFECTAIR Devices** and includes all related activities other than **Design**, including without limitation, purchase, storage and inspection of raw materials/components through molding, assembly, in-process inspections, storage of in-process assemblies, **Labeling**, packaging, final inspection and storage and handling of finished package product.
3.26. "**Party**" means **DSCO** or **LACEY** and, when used in the plural, means both **DSCO** and **LACEY,** or their respective transferees.
3.27. "**Preparatory Activities**" has the meaning set forth in the Background Section of this **Agreement**.
3.28. "**Program**" has the meaning set forth in Section 1 of this **Agreement**.
3.29. "**Program-related Intellectual Property**" has the meaning set forth in Section 7.2.4.
3.30. "**Purchase Order**" means a **DSCO** purchase order issued pursuant to this **Agreement** providing for **LACEY Services**, which has been executed by both **Parties** and contains the material terms of the **Services**, including either the **LACEY** proposal for, or a description of, the **Services** being authorized thereunder, timing, pricing, and other requirements, restrictions or agreements of the **Parties** related thereto. "**Purchase Order**" includes a **DSCO** purchase order for production supply as defined in Section 8.4. All **Purchase Orders** shall be in **US** dollars.

3.31. **"Regulatory Authority**" means any applicable federal, state, local, or foreign regulatory agency, department, bureau, or other governmental agency (including a court of competent jurisdiction) and includes for the purposes of this Agreement an ISO Certified Body.
3.32. "**Quality Agreement**" has the meaning set forth in Section 1.
3.33. "**Quality System Regulation**" or "**QSR**" means the **FDA**'s quality system requirements applicable to manufacturers of finished devices, codified at 21 C.F.R. Part 820.
3.34. "**Representatives**" means a **Party**'s directors, officers, employees, consultants, attorneys, accountants, advisors, **Affiliates** and agents and other parties who may receive **Confidential Information** in furtherance of the **Program**.
3.35. "**SEC**" means the U.S. Securities and Exchange Commission.
3.36. "**Services**" has the meaning set forth in Section 4 of this **Agreement**.
3.37. "**Specifications**" means the specifications for each of the **AFECTAIR Devices** as set forth in each **Purchase Order** and as described in Section 12.1.
3.38. "**Term**" has the meaning set forth in Section 2.
3.39. "**US**" means United States of America.

Development Agreement

4. **LACEY**'s development activities under this **Agreement** (the "**Services**") include providing regulatory, planning, and development support for the introduction of the **AFECTAIR Devices** for commercial distribution in the **US** and/or **EU**, **Manufacture** of **AFECTAIR Devices**, and such other activities related thereto as provided in this **Agreement** and in any **Purchase Order** issued under this **Agreement**.
5. Development and qualification activities from and after the date of this **Agreement** will be quoted based on identified deliverables and incorporated into a **Purchase Order**.
   5.1. The terms of a**Purchase Order** shall not be subject to change, except as agreed by the **Parties**. If the scope of **Services** in a **Purchase Order** is expanded or otherwise changed, **LACEY** shall have the opportunity to revise the quotation. If any such revised quotation is not acceptable to **DSCO**, **DSCO** may determine to cease the activities and terminate such **Purchase Order**, in which event **LACEY** shall cease its activities under such **Purchase Order** as promptly as possible and **DSCO** shall pay **LACEY** for the **Services** provided prior to termination.
   5.2. **LACEY** is authorized to purchase on **DSCO'S** behalf the **Equipment** (the "**Equipment**") listed in Appendix A-2 which is specially required for the performance of the **Services**; provided that (i) the **Parties** enter into a **Purchase Order** detailing the **Equipment** as and when ordered, and (ii) an **Equipment Purchase Order** Addendum is entered into by the **Parties** in connection with each **Equipment Purchase Order** in the form attached hereto as Addendum I to Schedule A. **DSCO** shall issue **Purchase Order**s to **LACEY** at quoted prices for the purchase and installation of such **Equipment**.
6. **DSCO** has responsibility for the following with regard to the **AFECTAIR Devices** and as reflected in Section 12.1:
   6.1. Devising and supplying product**Specifications**;

6.2. Devising and supplying product acceptance criteria, including defect identification and a sampling plan;
6.3. Approval of and responsibility for an overall**AFECTAIR Devices** validation strategy;
6.4. Approval of protocols for IQ/OQ/PQ builds to support the process validation strategy to be provided by**LACEY**; and
6.5. Design Control and Device Master record approval in accordance with**FDA GMP** and **ISO13485** requirements.

Intellectual Property

7. The funding of all **Intellectual Property**, research & development, regulatory affairs, clinical activities, if any, and claims of equivalency to other products related to the **AFECTAIR Devices** will be the responsibility of **DSCO,** except as provided in Section 7.2.1.
   7.1. Each of**DSCO** and **LACEY**, as applicable, shall own
      7.1.1. [***]
      7.1.2. [***]
   7.2. With respect to all**Inventions** conceived, created, and reduced to practice after the **Initial Contact Date** solely by or on behalf of either **Party** or jointly by or on behalf of the **Parties**, such **Inventions** shall be owned as follows:
      7.2.1. **LACEY** shall have the exclusive ownership of any [***] (collectively "**LACEY Improvements**"). **LACEY** shall assume full financial responsibility over **Lacey Improvements**.
      7.2.2. **DSCO** shall have the exclusive ownership of any [***], excluding **LACEY Improvements** and including, without limitation, [***] ,(y) **DSCO's** [***] (collectively **"DSCO Improvements"**). **DSCO** shall assume full financial responsibility for **DSCO Improvements**.
      7.2.3. **DSCO** shall have the exclusive ownership of any [***] (collectively "**Joint Improvements**"). [***] shall assume full financial responsibility over **JOINT Improvements**.
      7.2.4. For the purposes of this **Agreement**, "**Program-related Intellectual Property**" includes **DSCO Improvements**, **LACEY Improvements**, and **Joint Improvements**.
   7.3. During the**Term** and solely for the purposes of performing their respective obligations under this **Agreement**, each of **DSCO** and **LACEY** hereby grants to the other **Party** a non-exclusive, non-transferable, royalty-free and limited license to use the **Program-related Intellectual Property.** The rights granted under this Section 7.3 shall expire immediately upon expiration or termination of this **Agreement**.
   7.4. Each**Party** shall maintain records in sufficient detail and in good scientific manner appropriate for patent prosecution purposes to reflect properly all work done and results achieved in conducting its work hereunder, and shall respond to reasonable requests of the other **Party** for information regarding **Program-related Intellectual Property** in which the other **Party** has an ownership interest.
   7.5. In the event that**LACEY** shall determine to prosecute a patent relating to **LACEY Improvements**, as soon as practicable prior to any contemplated filing, **LACEY** shall submit a substantially completed draft of the applicable patent to **DSCO** for review and comment, which comments shall be considered in good faith. Should **DSCO** reasonably and in good faith, based on an opinion of counsel (including internal counsel), a copy of which will be supplied to **LACEY**, object to such proposed filing on the grounds that it would detrimentally affect, or would have an unreasonable risk of detrimentally affecting the confidentiality of **DSCO's Intellectual Property** rights (including, without limitation, its trade secrets and know-how), then **DSCO** shall be entitled to require **LACEY** to amend its filing to the extent necessary to protect **DSCO's Intellectual Property** rights.

7.6. During the**Term**, **LACEY** shall mark or have marked all finished goods containers or packages of **AFECTAIR Devices** with appropriate patent numbers and notices that **DSCO** will provide.

Supply Agreement

8. Pricing.
   8.1. Until such time as one or both the **AFECTAIR Devices Manufactured** by **LACEY** for **DSCO** reach steady-state **Manufacture** and a price list is created, unit transfer pricing for all products **Manufactured** by **LACEY** for **DSCO** will be established by written individual quotations that will be incorporated into a **Purchase Order**. The **Parties** agree that an initial indicative price list based on currently defined **DSCO** specification is reflected in **LACEY's** proposal dated August 12, 2011. With the consent of **DSCO**, which shall not be unreasonably withheld, the pricing to be incorporated into any **Purchase Order** shall be subject to amendment as agreed by the **Parties** based on changes in the **Specifications** and cost of raw materials, etc.
   8.2. **LACEY** will be responsible for all production aspects of the **AFECTAIR Device Program**, including supplier management for tooling, raw materials, purchased and manufactured components, assembly, and packaging.
   8.3. **DSCO** agrees to supply **LACEY** monthly with a rolling six-month forecast for the production of **AFECTAIR Devices**. **DSCO** will be financially responsible for materials, work in process, and finished goods conforming to **Specifications** for [***]
      8.3.1. **LACEY** will take reasonable care to minimize financial exposure of **DSCO** as far as is practical based on lead-time requirements.
   8.4. **Purchase Orders** for commercial product shall be supplied by **DSCO** with the following minimum information:
      8.4.1. P.O. Number;
      8.4.2. Date of P.O.;
      8.4.3. Part Number being ordered;
      8.4.4. Revision of part number being ordered;
      8.4.5. Quantity of part number being ordered;
      8.4.6. Requested delivery date;
      8.4.7. Delivery address of products;
      8.4.8. Product Specification number(s);
      8.4.9. Revision of Product Specification(s); and
      8.4.10. Other instructions as applicable.
   8.5. **LACEY** will supply **DSCO** with an Order Confirmation accepting the order as specified or identifying any changes required to fulfill the order.
   8.6. It is understood by both**Parties** that [***] for **DSCO AFECTAIR Devices** and that, [***]
   8.7. All proposals and**Purchase Order**s shall be denominated in **US** dollars.

Regulatory Matters

9. General. **DSCO** and **LACEY** shall each comply in all material respects with all applicable **Laws** that pertain to the activities for which **DSCO** and **LACEY** are each responsible under this **Agreement**, as described in Appendix A and in accordance with the **Quality Agreement**. 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 the **AFECTAIR Devices**.
10. Non-transferability of Duties. **LACEY** shall not transfer or assign any of its duties or responsibilities under this **Agreement** without prior written approval of **DSCO**.
11. Regulatory Approvals; **Labeling**. **DSCO** shall be responsible for compliance with all premarket requirements under Section 510(k) of the FDC Act and the applicable **Laws** of **EU** countries, as applicable to the **AFECTAIR Devices**. **DSCO** shall be responsible for obtaining and maintaining premarket notification (510(k)) clearance for **AFECTAIR Devices** or determining that there is an applicable 510(k) exemption, as required by the FDC Act and its implementing regulations. **DSCO** shall be responsible for the design and content of the **Labeling** of **AFECTAIR Devices**, and ensuring that the **Labeling** complies with all applicable **Laws**, including the FDC Act and its implementing regulations.
12. Quality System.
    12.1. General; **QSR** Requirements. **DSCO** and **LACEY** shall each operate in substantial compliance with all applicable **Laws**, including the **FDA** current good manufacturing practice (cGMP) requirements set forth in the **Quality System Regulation**s. Each **Party** shall bear its own costs and expenses related to **QSR** compliance. **DSCO** shall be responsible to finalize **Specifications** for each **AFECTAIR Device**, which shall be counter-signed and dated by both **Parties** and issued by **DSCO** to **LACEY** for **AFECTAIR Devices** inclusion in the **LACEY** quality system. The **Specifications** will contain drawings, raw material and packaging component requirements, and/or product performance requirements as necessary. The **Specifications** will bear a version number controlled by **DSCO**. The **Specifications** may only be amended or changed by a writing signed by both **Parties**, as described in Section 14.1.
    12.2. **Manufacturing** Activities. **LACEY** shall **Manufacture** all **AFECTAIR Devices** in substantial compliance the **QSR** and **ISO 13485** requirements, and the terms and conditions of the **Quality Agreement**, this **Agreement**, each applicable **Purchase Order**, and the **Specifications**.
13. Packaged Product Storage and Shipment: **LACEY** shall store all finished and packaged **AFECTAIR Devices** in substantial compliance with all applicable **Laws**, including the **QSR** and **ISO 13485** requirements, and the terms and conditions of the **Quality Agreement**, this **Agreement**, each applicable **Purchase Order**, and the **Specifications**. **LACEY** will handle and load finished and packaged **AFECTAIR Devices** onto transport carriers designated by **DSCO** in conformance with all applicable **Laws**, including the **QSR** and **ISO 13485** requirements, and the terms and conditions of the **Quality Agreement**, this **Agreement**, each applicable **Purchase Order**, and the **Specifications**. **DSCO** shall be responsible for the shipment of all finished and packaged **AFECTAIR Devices**
14. **Manufacturing** Changes**. LACEY** shall not make any changes, including the use of non-conforming materials, components, or assemblies used in the **Manufacture** of th**e AFECTAIR Devices** without documenting the change pursuant to **A LACEY** engineering document change notice (DCN), which shall not be effective until approved, counter-signed, and dated by **a DSCO Representative**. Temporary change notices (TCN) or deviations shall also include th**e DSCO Representative**'s counter-signature and date. **DSCO** shall review and respond to documentation submitted by **LACEY** for review or approval within 5 **Days** of receipt.

14.1. [***], may make changes to the **Design** of the **AFECTAIR Devices**. Changes to **Specifications** relating to **Manufacture**, quality, or other **LACEY** procedures will require a **DSCO** Engineering Change Order (ECN) and subsequent **LACEY** DCN, which shall be counter-signed and dated by both **Parties**. Each **Party** will respond to submitted documentation within 5 **Days** of receipt.

15. Product Review. **LACEY** shall provide **DSCO** with documentation of review and approval of each production lot of finished products prior to their release in the form of a Certificate of Conformity (CoC), in such form as shall be acceptable to both **Parties**. Each CoC must be signed and dated by a **LACEY Representative** and thereafter countersigned and dated by a **DSCO Representative** within 5 **Days** of receipt.
16. Post-Market Modifications. Any regulatory filings incident to change(s) in **Manufacturing** and/or **Specifications** shall be the responsibility of **DSCO**.
17. Product Returns; Complaints; Adverse Events.
    17.1. Any investigation, response or other action incident to product returns or complaints and/or adverse events shall be the responsibility of**DSCO**. **LACEY** shall cooperate fully with **DSCO** in investigating and resolving returns or customer complaints concerning the **AFECTAIR Devices**, and shall take such action to promptly resolve such complaints as may be reasonably requested by **DSCO**. The **Parties** shall establish and implement a system for exchange of complaint and adverse event information sufficient to allow the **Parties** to comply with all applicable regulations, which shall include appropriate provisions for recording customer complaints relating to **AFECTAIR Devices** and prompt notice to the other **Party** of significant and/or potentially reportable adverse events. Each **Party** shall provide accurate and timely information about complaints and adverse events to the other **Party**, when applicable, and shall otherwise cooperatively undertake investigations and provide information and analyses as reasonably requested by the other **Party** and as necessary to support **DSCO'S** fulfillment of complaint handling and Medical Device Reporting (MDR) requirements (21 C.F.R. Part 803) requirements. Each **Party** shall bear its own costs and expenses in fulfilling its obligations under and in accordance with this Section 17.1.
    17.2. **DSCO** shall be responsible to ensure substantial compliance with all applicable **Laws** pertaining to product returns, complaint handling and the reporting of adverse device events, including **FDA**'s complaint handling requirements under the **QSR**s (21 C.F.R. § 820.198) and the MDR. Both **Parties** shall cooperate to submit a request to **FDA** under 21 C.F.R. § 803.19(c) to exempt **LACEY** from the MDR requirements, and to allow **DSCO** to satisfy the reporting obligations for both **Parties**. Each **Party** shall bear its own costs and expenses in fulfilling its obligations under and in accordance with this Section 17.2.
18. Recalls; Corrections and Removals. All recall actions will be issued by **DSCO**. If **LACEY** becomes aware of any defect, problem, or adverse condition in any **AFECTAIR Devices**, **LACEY** shall promptly notify **DSCO**. **LACEY** shall cooperate fully with **DSCO** in investigating and resolving any correction, removal or field action. Each **Party** shall bear its own cost and expenses of any correction, removal, or field action. Each **Party** shall use reasonable efforts to ensure substantial compliance with all applicable **Laws** pertaining to corrections and removals, including voluntary actions under 21 C.F.R. Part 7 and **FDA**'s reporting requirements of corrections and removals under 21 C.F.R. Part 806. Each **Party** shall provide the other **Party** with advance copies of all filings to be made with the **FDA** under this Section 18.

19. Audits and Inspections.
    19.1. **LACEY** shall provide **DSCO** or **DSCO'S Representatives** reasonable access upon reasonable prior notice to inspect, review, and audit the **LACEY** facility(ies) where the **AFECTAIR Devices** are being **Manufactured** for the purpose of confirming that all **AFECTAIR Devices** are **Manufactured** in accordance with applicable **Laws** and the terms of this **Agreement**. In connection with any such inspection, review, or audit, **LACEY** shall allow **DSCO** or its **Representatives** to review and inspect the applicable facility(ies) and records, and to meet with **LACEY** personnel to discuss whether **LACEY**'s procedures and record-keeping are compliant with applicable **Laws**. Such inspections, reviews, and audits can take place on reasonable notice to **LACEY** and shall be conducted during normal business hours and in a manner intended to not unreasonably disrupt the normal operations of **LACEY**. **DSCO** may review but not copy **LACEY** procedure documents.
    19.2. **LACEY** shall advise **DSCO** within one business day if an authorized agent of the **FDA** or other **Regulatory Authority** inspects, reviews, or audits **LACEY**'s manufacturing facility(ies), and/or if the **Regulatory Authority** requests or requires information or changes that directly pertain to the **AFECTAIR Devices** or that may negatively impact **LACEY**'s ability to continue to **Manufacture AFECTAIR Devices** under this **Agreement**. **LACEY** shall provide **DSCO** with copies of all correspondence from a **Regulatory Authority** regarding the inspection, review, or audit of **LACEY** operations related to the **AFECTAIR Devices**, which may include, without limitations, facility registration or ISO certification changes or updates, Establishment Inspection Reports, Form **FDA** 483s, or equivalent forms issued by other Regulatory Authorities, and warning or untitled letters. **DSCO** shall have the opportunity to review and comment on **LACEY**'s written responses to a **Regulatory Authority** and shall assist **LACEY** to address any **Regulatory Authority** inquiry or investigation related to the **AFECTAIR Devices**.
    19.3. **DSCO** shall advise **LACEY** within one business day if an authorized agent of the **FDA** or other **Regulatory Authority** audits the **AFECTAIR Devices** and/or if the **Regulatory Authority** or requests or requires information or changes that directly pertain to the **Manufacture** of **AFECTAIR Devices** or that may negatively impact **LACEY**'s ability to continue to **Manufacture AFECTAIR Devices** under this **Agreement**. **LACEY** shall assist **DSCO** in responding to an inquiry from a **Regulatory Authority**, as a result of an inspection, review, or audit of **DSCO**'s operations related to the **AFECTAIR Devices**.
    19.4. Each**Party** shall notify the other **Party** if it becomes aware of a pending or existing administrative or government court-initiated action against the **Party**, including, but not limited to, seizures, injunctions, and criminal prosecution, that may affect the **Party**'s ability to comply with the terms of this **Agreement.**
20. **FDA** Debarment Certification. **LACEY** represents and warrants that, after due inquiry, it shall 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 or on behalf of **DSCO**, **LACEY** shall within 5 **Days** confirm in writing that it has complied with the foregoing obligation.

21. Payment.
    21.1. Payment terms for **Services** related to **AFECTAIR** development, qualification and **Manufacturing** will be included in individual **Purchase Order**s. Information on payment, security interest, delivery terms, risk of loss, shipment dates, cancellation, and special orders are included in the terms and conditions set forth on Appendix A-1.
    21.2. Notwithstanding any other provision of this Section 21, if **DSCO** in good faith disputes all or a portion of a **LACEY** invoice, then **DSCO** shall pay any undisputed amount and shall promptly provide **LACEY** a written explanation of the reasons for the dispute and the related amount. The **Parties** shall work together in good faith to resolve any dispute within 30 calendar **Days**. The time period may be extended by mutual agreement of the **Parties**. If the **Parties** are unable to resolve the dispute, either **Party** may refer the matter to arbitration in accordance with Section 27. During the pendency of any dispute, **LACEY** shall continue to perform **Services** under this **Agreement**.
    21.3. If any term of this **Agreement** conflicts with any term of an accepted **Purchase Order**, the terms set forth in this **Agreement** shall supersede the conflicting terms in such **Purchase Order**, except to the extent that such **Purchase Order** expressly states in a document signed separately by both **Parties** that they intend to vary the terms of this **Agreement** as it applies to such **Purchase Order**.
22. Warranties.
    22.1. **LACEY** warrants only that the goods delivered hereunder will conform to the **Specifications** provided by **DSCO** and will be free from defects in material or workmanship.
    22.2. There are no other warranties other than those contained in each acknowledged **Purchase Order**.
    22.3. **LACEY** makes no warranty of merchantability or fitness for purpose of the goods covered by this **Agreement**.
23. Indemnification.
    23.1. **DSCO** shall indemnify, defend and hold harmless **LACEY**, its parents and **Affiliates** and each of their respective employees, officers, directors and agents (hereinafter "**LACEY Indemnified Parties**") from and against any and all damages, liabilities, claims, costs, charges, judgments and expenses (including reasonable attorney's fees) (collectively "**Damages**") that may be sustained, suffered or incurred by **LACEY**, or **LACEY** Indemnified **Parties** arising directly from (1) the breach by **DSCO** of any warranty, representation, covenant, or agreement made by **DSCO** in this **Agreement**; (2) any product liability or personal injury claim by third parties arising from the **Design**, sale, distribution or indicated use of any product that meets **DSCO'S** quality requirements and **Specifications** and is not otherwise defective; and (3) any claim that any product **Manufactured** by **LACEY** under this **Agreement** or the use or sale thereof infringes any patent of any third party, except to the extent that such claim is based on **LACEY Intellectual Property** or **LACEY Improvements**.

23.2. **LACEY** shall indemnify, defend and hold harmless **DSCO**, its parents and **Affiliates** and each of their respective employees, officers, directors and agents (hereinafter "**DSCO Indemnified Parties**") from and against any and all **Damages** that may be sustained, suffered or incurred by **DSCO** or **DSCO** Indemnified **Parties** arising directly from (1) the breach by **LACEY** of any warranty, representation, covenant or agreement made by **LACEY** in this **Agreement** – provided that **LACEY** shall not be liable for any product liability or personal injury claims by third parties arising from the **Design**, sale, distribution, or indicated use of any product which meets **DSCO** quality requirements and **Specifications** and is not otherwise defective; (2) any claim raised by any **LACEY** employee(s) or other persons against **DSCO** and **DSCO** Indemnified **Parties** in connection with possible injuries suffered when using or servicing any of the **DSCO-**owned **Equipment** located on **LACEY**'s premises, (3) **LACEY's** use of the **Equipment**, (4) any alleged violation of any environmental requirements in the **Manufacture** of **AFECTAIR Devices**, and (5) any third-party claim that any product purchased from **DSCO** made in accordance with **LACEY Intellectual Property** or **LACEY Improvements** or the use or sale thereof infringes any patent of any third party.

23.3. **LACEY** shall indemnify **DSCO** for all claims, demands, suits, or actions which may be asserted against **DSCO** for any kind of losses related to defects in materials and/or workmanship of the **AFECTAIR Devices**.

23.4. EXCEPT FOR INFRINGEMENT OF**INTELLECTUAL PROPERTY** RIGHTS OR AS NECESSARY TO SATISFY A THIRD PARTY CLAIM INDEMNIFIED HEREUNDER AND/OR IN THE EVENT OF A BREACH OF ITS CONFIDENTIALITY OBLIGATIONS SET FORTH IN SECTION 28 OF THIS **AGREEMENT**, UNDER NO CIRCUMSTANCES SHALL **LACEY**'s TOTAL LIABILITY TO DISCOVERY LABS IN CONNECTION WITH THE SUBJECT MATTER OF THIS **AGREEMENT**, INCLUDING, WITHOUT LIMITATION, THE **AFECTAIR DEVICES** OR ANY SERVICES PROVIDED IN CONNECTION WITH THE **AFECTAIR DEVICES**, [***].

23.5. EXCEPT FOR INFRINGEMENT OF**INTELLECTUAL PROPERTY** RIGHTS OR AS NECESSARY TO SATISFY A THIRD PARTY CLAIM INDEMNIFIED HEREUNDER AND/OR IN THE EVENT OF A BREACH OF ITS CONFIDENTIALITY OBLIGATIONS SET FORTH IN SECTION 28 OF THIS **AGREEMENT**, 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 PROGAM CONTEMPLATED BY THIS **AGREEMENT**, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY. NOTWITHSTANDING THE FOREGOING, DIRECT DAMAGES OF A **PARTY** WITH RESPECT TO A THIRD PARTY CLAIM SHALL INCLUDE ALL DAMAGES AWARDED TO SUCH THIRD PARTY, INCLUDING ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES.

24. Procedure for Indemnification.

24.1. In the event that any person (an "**Indemnified Party**") entitled to indemnification under Section 23 is seeking indemnification, such Indemnified **Party** shall promptly notify the indemnifying **Party** ("**Indemnitor**") in writing of the claim (and in reasonable detail); *provided*, *however,* that failure to give such notification shall not affect the indemnification to be provided hereunder except to the extent Indemnitor shall have been actually prejudiced as a result of such failure. As a condition to indemnification under this **Agreement**, Indemnitor, in its sole discretion, may manage and control, at its sole expense, the defense of the claim and its settlement. The **Indemnified Parties** shall provide Indemnitor with reasonable assistance and cooperation and all material relevant information to support the defense of any indemnified claim, and Indemnitor shall reimburse the Indemnified **Parties** for their reasonable out-of-pocket expense incurred in connection with such assistance and cooperation. Indemnitor 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 **LACEY Indemnified Parties** or the **DSCO Indemnified Parties** without the prior written consent of such affected **Indemnified Party**, as applicable. **Indemnitor** shall have no obligation to indemnify the **Indemnified Parties** in connection with any settlement made without **Indemnitor**'s written consent. Except for such assistance and cooperation as may reasonably be requested by **Indemnitor**, nothing contained in this Section 24 shall require the **Indemnified Party** to take any action in its own name in defending any claim, action or proceedings; *however*, the **Indemnified Party**, at is 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 the **Indemnified Party**, representation of the **Indemnified Party** by the counsel retained by **Indemnitor** 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 **Indemnitor** 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 **Indemnitor**'s counsel may be retained to represent the **Indemnified Party** at **Indemnitor**'s expense. As the **Parties** intend complete indemnification, all reasonable attorneys' fees and expenses incurred by an Indemnified **Party** in connection with enforcement of Sections 23.1, 23.2, and 23.3 shall also be reimbursed by **Indemnitor**.

24.2. If**LACEY** receives a written legal opinion or notification that the **Manufacture**, sale, or use of **AFECTAIR Devices** infringe on the proprietary information or patents of a third party, **LACEY** shall promptly deliver a copy of such opinion or notification to **DSCO**. **LACEY** may discontinue **Manufacture** of any goods involved in the alleged infringement with prior written notice to **DSCO** provided that **DSCO** is given a reasonable period of time to ascertain the legitimacy of such opinion or notice and discuss with **LACEY**. In the event **DSCO** believes (upon the advice of its counsel, including internal counsel) that neither the **Manufacture**, sale, nor use of **AFECTAIR Devices** infringe on the proprietary information or patents of such third party, in order to ensure continuous availability of **AFECTAIR Devices Manufacture** by **LACEY**, **DSCO** may notify **LACEY** that it wishes to continue the **Manufacture** of **AFECTAIR Devices** and, in connection therewith, will indemnify **LACEY** in accordance with Section 23.1. Upon receipt of such notice, **LACEY** will continue to **Manufacture AFECTAIR Devices**.

25. Insurance.

25.1. Each**Party** shall at all times maintain all necessary insurance coverage with sound and reputable independent insurers at commercially reasonable levels of coverage or shall be self insured at levels that are consistent with industry practice, having regard to the nature, type, scope and size of the business it conducts and all its respective activities and obligations under this Agreement, which shall include, at a minimum: (i) comprehensive general liability insurance, including property damage, for injury to persons or damage to property; (ii) workers compensation and employers' liability coverage with required statutory limits for workers compensation and employers liability limits: (iii) property insurance covering the **AFECTAIR Devices**, molds and tooling, and **DSCO** materials and **Equipment**; and (iv) products liability insurance, which, if the policy is a claims-made policy, includes coverage for a period of at least 10 years after the performance of the Program. Each **Party** shall make reasonable commercial efforts to insure that all of its insurance policies shall be issued by "A-rated" insurers as designated by Standard and Poor's Corporation or A.M. Best. Each **Party** shall, upon reasonable request of the other **Party**, produce satisfactory evidence that all insurance premiums have been paid and kept up to date and are kept in accordance with local insurance laws or regulations from time to time in force, or shall furnish appropriate certificates of insurance showing proof of coverage. The insurance coverage may be provided through a combination of primary, excess/umbrella or self-insured retention, and shall not serve to operate as a limitation on the recovery of any claim. Each **Party** shall include the other **Party** as a named insured on its policies of insurance, as the other **Party**'s interests may be affected pursuant to this Agreement.

25.2. The requirement for insurance shall not be construed to establish a limit on liability hereunder. Upon the request of a Party, the other**Party** shall furnish to the requesting **Party** a certificate of insurance evidencing the coverage provided in this Section 25 as of such date, pursuant to which the insurer agrees to notify such other **Party** 30 days in advance of any coverage change, nonrenewal or cancellation. In the case of a coverage change, nonrenewal or cancellation, the affected **Party** shall provide the other **Party** with a new certificate of insurance evidencing the coverage provided in this Section 25.

26. Force Majeure.

26.1. Neither**Party** shall be responsible or liable, or deemed in breach hereof, to the extent the performance of its obligations hereunder is delayed or prevented due solely to circumstances beyond the reasonable control and without the fault or negligence of the **Party** experiencing such impediment to performance (such causes hereinafter called "Force Majeure"). Such causes may include but shall not be limited to acts of God; unusually severe weather; war; riots; fire; actions or failures to act on the part of governmental authorities which delay or prevent performance; or the **Party**'s inability despite due diligence to obtain required licenses. In the event either **Party** is delayed or rendered unable to perform due to Force Majeure, the affected **Party** shall give prompt notice of the conditions and the expected duration to the other **Party** promptly after the occurrence of the cause relied upon, and upon the giving of such notice the obligations of the **Party** giving the notice will be suspended during the continuance of the Force Majeure for a period [***] or as agreed upon in writing by the **Parties**.

27. Arbitration.

27.1. Any controversy or claim arising out of or relating to this**Agreement** or the validity, inducement or breach thereof, shall be settled by binding arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("**AAA**") then pertaining, except where the rules conflict with this provision, in which case this provision shall control. The **Parties** hereby consent to the jurisdiction of the federal district court for the district in which the arbitration is held for the enforcement of this provision and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction shall enforce this clause and enter judgment on any award. The arbitrator shall be an attorney with at least 15-years experience with a law firm, corporate law department, or as a judge in a court of general jurisdiction. The arbitration shall be held in New York City or such other venue as is agreeable to both **Parties**. In rendering the decision, the arbitrator shall apply the substantive law of Connecticut (except where the law conflicts with this clause) except that the interpretation and enforcement of this provision shall be governed by the Federal Arbitration Act. The arbitrator shall be selected from a panel of qualified arbitrators of AAA. Within forty five (45) days of initiation of the arbitration, the **Parties** shall reach agreement upon the procedures to be followed. Failing such agreement, AAA will design and the **Parties** shall follow procedures that are reasonably designed to conclude the arbitration within eight (8) months. **Each Party has the right before and during the arbitration to seek and obtain from the appropriate court provisional remedies, including but not limited to, attachment, preliminary injunction and replevin in order to avoid irreparable harm. THE ARBITRATOR SHALL NOT AWARD ANY PARTY PUNITIVE, EXEMPLARY, MULTIPLIED, CONSEQUENTIAL DAMAGES AND EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT TO SEEK SUCH DAMAGES. NO PARTY MAY OBTAIN PREJUDGMENT INTEREST, ATTORNEYS' FEES OR COSTS.**

28. Confidentiality.

28.1. Each**Party** acknowledges and agrees to maintain the confidentiality of all **Preparatory Activities** and negotiations undertaken in connection with the **Program** and **Services** and the other **Party**'s respective **Confidential Information**, in each event in accordance with the Mutual Confidential Disclosure **Agreement** between the **Parties**, dated as of November 24, 2010 (the "CDA"), which shall survive execution of this **Agreement**. **DSCO** and **LACEY** hereby agree to amend the CDA by extending the period provided in Section 16 of the CDA for a period ending five (5) years after the date of expiration or earlier termination of this **Agreement**. Further, the **Parties** acknowledge and agree that any future **Supply Agreements** shall contain mutually agreeable terms and conditions with respect to the **Parties**' obligations of confidentiality with regard to **Confidential Information** on terms substantially similar to the CDA.

28.2. Neither**Party** shall disclose the terms of this **Agreement** to a third party, except for legal, financial, accounting or other similar advisors who agree to keep the terms of this **Agreement** confidential, without the prior written approval of the other **Party**, or as otherwise required by law. Furthermore, neither **Party** will originate any publicity, news release, or other public announcement, written or oral, whether to the public press, to stockholders, or otherwise, relating to this **Agreement**, to any amendment hereto or to performance hereunder or the existence of an arrangement between the **Parties** without the prior written approval of the other **Party**. However, nothing herein shall prevent a **Party** from disclosing **Confidential Information** on a need-to-know basis to an employee of its parent corporation or any other corporation under common ownership and control; providing said employees are informed of the confidential nature of the information and further provided that each **Party** shall be liable for any violation of the provisions of this **Agreement** that occur as the result of the conduct of any employee of the parent or any employee of a company under common ownership and control with such **Party**.

28.3. Notwithstanding anything to the contrary in this**Agreement**, **LACEY** acknowledges and agrees that, if **DSCO** determines in its sole judgment to do so, **DSCO** may describe the material terms of this **Agreement** and any future **Supply Agreement** in any of its reports and filings with the **SEC** and may file a copy of this **Agreement** and any future **Supply Agreements** with the **SEC**, as well as incorporate the descriptions and this **Agreement** (and any **Supply Agreements**) by reference into other **SEC** filings. In such event, **DSCO** will notify **LACEY** and request that the **SEC** agree to confidential treatment of sensitive terms contained in this **Agreement** or any future **Supply Agreements** to the extent such confidential treatment is reasonably available to **DSCO**.

29. Asset Management.

29.1. **DSCO**, as owner of the **Equipment**, molds and tooling, and other capital assets used in the production of the **AFECTAIR Devices**, will be responsible for the purchase price and the cost of installation, maintenance and other related expenses. Such assets include but are not limited to the **Equipment** listed on Appendix A-2, as amended from time to time, purchased by **LACEY** on **DSCO'S** behalf.

29.2. **LACEY** shall enter into and attach to each **Equipment Purchase Order** an **Equipment** Addendum substantially in the form included in Appendix A-2. **LACEY** agrees that it will provide information concerning its facility as may reasonably be requested by **DSCO** in order to schedule the **DSCO** assets located on **LACEY**'s premises under **DSCO'**s insurance policies.

30. Termination.

30.1. **DSCO** may terminate this **Agreement**:

30.1.1. Upon [***] to **LACEY** of plans to discontinue the **Program,** [***].

30.1.2. If such termination is made [***], upon [***] written notice to **LACEY**.

30.1.3. upon [***] notice to **LACEY** if (i) **LACEY** is unable to **Manufacture AFECTAIR Devices** substantially in accordance with the terms of an accepted **Purchase Order**; (ii) [***]; or (iii) if the **FDA** or other **Regulatory Authority** revokes, or provides any formal notification that reasonably could be expected to result in revocation of, any registration, certification or authorization that is required or necessary to **Manufacture AFECTAIR Devices** in accordance with this **Agreement**, the **Quality Agreement** or any applicable **Purchase Order**.

30.2. **LACEY** may terminate this **Agreement**:

30.2.1. Upon [***] notice of plans to discontinue **Manufacture** of the **AFECTAIR Devices**.

30.2.2. For cause, if **DSCO** fails to make any payment on the due date set forth in an accepted **Purchase Order** and does not remedy such failure [***].

30.3. Either**Party** may terminate this **Agreement**:

30.3.1. upon [***] notice to the other **Party** if the **Parties**, after a good faith effort, are unable to agree on [***]. For the purposes of this Section 30.3.1, "good faith effort" means that the **Parties** have negotiated in good faith and have escalated any irresolvable issues to their respective Presidents.

30.3.2. upon [***] notice to the other **Party**, if such other **Party** is in breach of any material obligation under this **Agreement** and such breach is not cured [***]; or

30.3.3. immediately, if the other **Party** (i) ceases for any reason to carry on business, dissolves, liquidates, winds up, or files or is petitioned into bankruptcy (and any such voluntary petition is not dismissed [***]), liquidation, rehabilitation or dissolution or (ii) becomes insolvent or fails generally to pay its debts or obligations or (iii) a petition is filed seeking the appointment of or the taking possession by a receiver, custodian, trustee or similar official.

31. Effects of Termination. Upon termination of this **Agreement**:
    31.1. **LACEY** will cooperate and provide reasonable assistance to **DSCO** to transfer (at **DSCO'S** expense) all **Equipment**, inventory and materials to any successor site or to such other location that **DSCO** may designate in writing. **DSCO** will issue **Purchase Order**s to **LACEY** to cover all reasonable costs related to the transfer and return of the **Equipment**, inventory and materials. Unless otherwise agreed, such reimbursement costs shall be consistent with the costs reflected in the two most-recent accepted **Purchase Order**s. [***].
    31.2. Each**Party** will return to the other **Party** or certify in writing to the other **Party** that it has destroyed all documents and other tangible items it or its employees or agents have received or created pursuant to this **Agreement** pertaining, referring or relating to the **Confidential Information** of the other **Party**, except that each **Party** may retain one (1) complete copy of **Confidential Information** for archival purposes to assure compliance with this **Agreement**
32. Amendments. Amendments, modifications, and additions to this **Agreement** must be made in writing and must be signed by authorized officers of the respective **Parties** hereto. No invoice, quotation, acknowledgment, **Purchase Order**, or other commercial document or instrument and no course of dealing shall be effective to modify any of the terms of this **Agreement**.
33. Notices. All notices to be given as required in this **Agreement** shall be in writing and may be delivered personally, or mailed either by a reputable overnight carrier with signature receipt or certified mail, postage prepaid to the **Parties** at the addresses set forth below or at such other address as either **Party** may provide by written notice to the other **Party** in accordance with the provisions of this Section 33. Any such notice shall be effective: (i) on the date sent, if delivered personally or by facsimile (receipt of which is confirmed); (ii) the date after delivery if sent by overnight carrier; or (iii) on the date received if sent by certified mail. Notices for the **Parties** shall be sent to:

If to Discovery:
Discovery Laboratories, Inc.
2600 Kelly Road
Suite 100
Warrington, PA 18976-3646
Attention: [***]
FAX: [***]

And with a required copy to:
Discovery Laboratories, Inc.
2600 Kelly Road
Suite 100
Warrington, PA 18976-3646
Attention: [***]
FAX: [***]

If to **LACEY**:
Lacey Manufacturing Company
1146 Barnum Avenue,
Bridgeport, Connecticut 06610
Attn: [***]
FAX: [***]

34. Entire Agreement. This **Agreement** and the CDA contain the entire understanding between the **Parties** with respect to development of the **AFECTAIR Devices** and the Project. Any representation, promise, or condition that is not incorporated herein shall not be binding upon either **Party**.
35. Assignment. Neither this **Agreement** nor any rights or obligations hereunder may be assigned, transferred, delegated, pledged, hypothecated, or encumbered by either **Party** without the prior written consent of the other **Party** hereto, except that the rights and obligations of either **Party** may be assigned to any entity that acquires substantially all of the relevant assets of the assigning **Party**, unless the acquisition is made by a direct competitor of the other **Party**, in which case either **Party** may terminate this **Agreement**. The sale of a controlling interest in the equity securities of a **Party** shall not be deemed an assignment hereunder.
36. No Waiver. Neither **Party** hereto shall be deemed to have waived the protection of any provision hereof, not its right to enforce the same upon a breach or subsequent breach thereof, unless such waiver shall be in writing and executed in a manner similar to the execution of this **Agreement**.
37. Counterparts. This **Agreement** may be executed in multiple counterparts, but all such counterpart documents shall constitute but one, single agreement.
38. Severability. In the event that one or more provisions of this **Agreement** is held to be invalid, illegal or unenforceable for any reason, the same shall not affect any other provision of this **Agreement**, but this **Agreement** will be construed as if such invalid, illegal or unenforceable provision had never been contained herein.
39. This **Agreement** is intended solely for the benefit of the executing **Parties**. No other person or entity shall have any rights under or in connection with this **Agreement**.

In witness whereof, authorized representatives of the **Parties** have executed this **Agreement**.

DISCOVERY LABORATORIES, INC.

By: W. Thomas Amick, Chief Executive Officer

Signature: /s/ W. Thomas Amick Date 2.2.2012

LACEY MANUFACTURING COMPANY, A DIVISION OF PRECISION ENGINEERED PRODUCTS, LLC

By: Kenneth Lisk, President
Signature: Kenneth Lisk Date 2.2.2012

APPENDIX A

AFECTAIR® **DEVICES PROGRAM**

LACEY SCOPE OF WORK

- PRODUCTS
    - AFECTAIR Small- Adapter only for infants
    - AFECTAIR Large- Adapter only for children and adults
    - AFECTAIR DUO Small- Adapter, tee, tubing for infants
    - AFECTAIR DUO Large- Adapter, tee, tubing for children and adults
- MANUFACTURING

[***]

- REGULATORY/QA

  [***]

- OTHER

  [***]

[***] Denotes Material is Subject to a Confidential Treatment Request

AFECTAIR Device Components

[***]

[***]

Terms and Conditions of Payment

See Appendix A-1

Equipment to be Purchased by LACEY

See Appendix A-2

TERMS AND CONDITIONS

[***]

INITIAL EQUIPMENT

[***]

[***] Denotes Material is Subject to a Confidential Treatment Request

[Form of] Equipment Addendum
[To be executed and appended to each Equipment Purchase Order]

Addendum to **Purchase Order** between Discovery Laboratories, Inc. ("**DSCO**") and Lacey Manufacturing Company ("**LACEY**").

Each of **DSCO** and **LACEY** agree that:

[***]

Discovery Laboratories, Inc.	Lacey Manufacturing Company, LLC
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____

[***] Denotes Material is Subject to a Confidential Treatment Request

EXHIBIT 10.2

DISCOVERY LABORATORIES, INC.
2011 LONG-TERM INCENTIVE PLAN
STOCK OPTION AGREEMENT

Employee

RECITALS

A. The Board has adopted the Discovery Laboratories, Inc. 2011 Long-Term Incentive Plan (the "Plan") for the purpose of encouraging selected Employees, directors and consultants of the Company and its Subsidiaries to acquire a proprietary interest in the growth and performance of the Company, to generate an increased incentive to contribute to the Company's future success and prosperity, thus enhancing the value of the Company for the benefit of its stockholders, and to enhance the ability of the Company and its Subsidiaries to attract and retain exceptionally qualified individuals upon whom, in large measure, the sustained progress, growth and profitability of the Company depend.

B. Participant is an Employee who will render valuable Services to the Company (or Subsidiary), and this Award Agreement is executed pursuant to, and is intended to carry out the purposes of, the Plan in connection with the Company's grant of an option to Participant.

C. All capitalized terms in this Stock Option Agreement ("Award Agreement") shall have the meaning assigned to them in the Plan. For convenience, relevant portions of certain of the Plan definitions and certain additional definitions relating to this Award Agreement are included in the Appendix. This Award Agreement, including the Notice of Grant, is subject to the terms of the Plan, which are incorporated in this Award Agreement by reference. If there is a conflict between the terms of the Plan and this Award Agreement or the Notice of Grant, the terms of the Plan shall prevail.

NOW, THEREFORE, it is hereby agreed as follows:

1. **Award of Option**. The Company hereby grants to Participant, as of the Award Date, an option to purchase up to the number of Option Shares specified in the Notice of Grant. The Option Shares shall be purchasable from time to time as specified in Paragraph 4 during the option term specified in Paragraph 2 at the Option Price set forth in the Notice of Grant.

2. **Option Term**. This option shall have a term commencing on the Award Date and ending on the Expiration Date set forth in the Notice of Grant. The option shall expire at the close of business on the Expiration Date, unless sooner terminated in accordance with Paragraph 5 or 6.

3. **Limited Transferability**. The option granted under this Award Agreement shall not be assignable, alienable, saleable, or transferable by Participant other than by will or by the laws of descent and distribution; provided, however, that, if a procedure shall be adopted by the Committee at any time, Participant may designate a beneficiary or beneficiaries to exercise the rights of Participant with respect to this option upon Participant's death. The option granted under this Award Agreement shall be exercisable during Participant's lifetime only by Participant or, if permissible under applicable law, by Participant's guardian or legal representative. This option may not be pledged, alienated, attached, or otherwise encumbered, and any purported pledge, alienation, attachment, or encumbrance thereof shall be void and unenforceable against the Company or any affiliate of the Company. Notwithstanding the foregoing, if this option is designated a Non-Qualified Stock Option in the Notice of Grant, then this option may, in connection with Participant's estate plan, be assigned, in whole or in part, during Participant's lifetime to one or more members of Participant's immediate family or to a trust established for the exclusive benefit of one or more such family members. The assigned portion shall be exercisable only by the person or persons who acquire a proprietary interest in the option pursuant to such assignment. The terms applicable to the assigned portion shall be the same as those in effect for this option immediately prior to such assignment and shall be set forth in such documents issued to the assignee as the Committee may deem appropriate.

4. **Dates of Exercise**. This option shall vest and become exercisable for the Option Shares in one or more installments as specified in the Notice of Grant. As the option becomes exercisable for such installments, those installments shall accumulate, and the option shall remain exercisable for the accumulated installments until the Expiration Date or sooner termination of the option term under Paragraph 5 or 6.

5. **Termination of Service**. The option term and this option shall expire and cease to be exercisable prior to the Expiration Date should any of the following provisions become applicable:

(a) If Participant's Service is terminated for any reason other than death, Disability or for Cause, then Participant shall have the right to exercise, in whole or in part, that portion of this option that was vested and exercisable on the date of termination of Service until the earlier of (i) three (3) months after termination of Service or (ii) the Expiration Date; and, to the extent that any portion of this option was not exercisable on the date of termination of Service, it will immediately terminate.

(b) If Participant's Service is terminated on account of death or Disability, then Participant or Participant's Beneficiary (as applicable) shall have the right to exercise, in whole or in part, that portion of this option that was vested and exercisable on the date of termination of Service until the earlier of (i) one (1) year after Participant's termination of Service or (ii) the Expiration Date; and, to the extent that any portion of this option was not exercisable on the date of termination of Service, it will immediately terminate.

(c) If Participant's Service is terminated for Cause or if Participant shall breach any post-Service duties to the Company or any post-Service covenants or agreements, including any confidentiality or non-competition and non-solicitation agreement, any unexercised portion of this option shall terminate immediately. Solely for the purposes of this Award Agreement, notwithstanding any notice period or cure period provided in any employment or other applicable agreement, if Participant is terminated for Cause, the date of termination shall be deemed to be the date on which the Company issues a notice of termination to Participant (subject to any right that the Participant may have to cure). The right to exercise any vested and unexercised portion of this option shall be suspended during any such notice or cure period. Should the Company revoke any notice of termination based on Participant's satisfactory cure under an employment or other applicable agreement, the Committee may reinstate the right to exercise this option under the original terms of this Award Agreement.

6. **Special Acceleration of Option**. Except as otherwise expressly provided in a Participant's employment or other applicable agreement, which shall supersede the provisions of this Paragraph 6 solely to the extent that the rights and privileges under such agreement, as determined by the Committee, in its discretion, are not reasonably likely to significantly diminish the rights and benefits that would otherwise be provided under this paragraph 6:

(a) In the event of a Change in Control, vesting under this option shall automatically accelerate so that, immediately prior to the effective date of the Change in Control, but subject to the occurrence of the Change in Control, this option shall become exercisable with respect to the total number of Option Shares at the time subject to this option and may be exercised for any or all of those Option Shares. However, vesting under this option shall not so accelerate if and to the extent: (i) this option is, in connection with the Change in Control, either to be assumed by the successor corporation (or parent thereof) or to be replaced with a comparable option to purchase shares of the capital stock of the successor corporation (or parent thereof), or (ii) this option is to be replaced with a cash incentive program of the successor corporation which preserves the spread existing on any unvested Option Shares at the time of the Change in Control (the excess of the Fair Market Value of those Option Shares over the aggregate Option Price payable for such Option Shares) and provides for subsequent pay-out in accordance with the same option vesting schedule set forth in the Notice of Grant. The determination of comparability under clause (i) above shall be made by the Committee, and its determination shall be final, binding and conclusive. Notwithstanding the foregoing, the Committee shall have the discretion, exercisable at any time during the option term, to provide for the automatic acceleration of all or a portion of this option upon the occurrence of a Change in Control, whether or not this option is to be assumed or replaced in the Change in Control.

(b) Upon the occurrence of the termination of Participant's Service by reason of an Involuntary Termination (as defined below) within eighteen (18) months following the effective date of a Change in Control, vesting under this option shall accelerate automatically and this option shall become exercisable with respect to the total number of Option Shares at the time subject to this option and shall remain exercisable until the earlier of (i) one year after the effective date of the Involuntary Termination, or (ii) the Expiration Date. Involuntary Termination shall mean the termination of the Service of any individual which occurs by reason of:

(i) such individual’s involuntary dismissal or discharge by the Company for reasons other than Cause, or

(ii) such individual’s voluntary resignation following (A) a change in his or her position with the Company (or Subsidiary employing such individual) which materially reduces such individual’s duties and responsibilities or the level of management to which such individual reports, (B) a reduction in such individual’s level of compensation (including base salary, fringe benefits and target bonus under any corporate performance-based bonus or incentive programs) by more than fifteen percent (15%) or (C) a relocation of such individual’s place of employment by more than fifty (50) miles, and farther from the Participant’s residence than prior to the relocation; provided and only if such change, reduction or relocation is effected by the Company without such individual’s consent; provided that such voluntary resignation shall not be an Involuntary Termination unless the Participant gives the Company written notice of the Participant’s intent to resign as a result of the existence of a specified condition described in (A), (B) or (C) within 90 days of the initial existence of such condition, provides the Company 30 days to cure such condition, and actually resigns no more than 10 days after the lapse of such 30-day cure period if the condition is not cured.

(c) This Award Agreement shall not in any way affect the right of the Company to adjust, reclassify, reorganize or otherwise change its capital or business structure or to merge, consolidate, dissolve, liquidate or sell or transfer all or any part of its business or assets.

7. **Repurchase Right.** If at any time Participant’s Service is terminated for Cause or if Participant shall breach any covenants set forth in any written agreement between Participant and the Company, the Company may, in its discretion, for a period of one (1) year after the termination for Cause or upon the actual discovery by the Company of the breach, whether or not within such 1-year period, as the case may be, and upon 10 (ten) days’ notice to Participant, (i) repurchase all or any portion of any Shares acquired by Participant upon Participant’s exercise of this option, and/or (ii) require Participant to repay to the Company the amount of any profits realized by Participant upon the sale or other disposition during the preceding three (3) years of any Shares acquired by Participant upon Participant’s exercise of this option. The purchase price for any Shares repurchased by the Company pursuant to clause (i) of this Paragraph 7 shall be the lesser of the price paid by Participant to acquire such Shares and the Fair Market Value thereof on the date of such repurchase by the Company. In addition, the Company shall have repurchase rights in accordance with the terms of any repurchase policy as may be in effect from time to time.

8. **Adjustment in Option Shares**. Should any change be made to the Shares of the Company by reason of any stock split, stock dividend, recapitalization, combination of shares, exchange of shares or other change affecting the outstanding Shares as a class without the Company's receipt of consideration, appropriate adjustments shall be made to (i) the total number and/or class of securities subject to this option and (ii) the Option Price in order to reflect such change and thereby preclude a dilution or enlargement of benefits hereunder.

9. **Stockholder Rights**. The holder of this option shall not have any stockholder rights with respect to the Option Shares until such person shall have exercised the option, paid the Option Price and become a holder of record of the purchased Shares.

10. **Manner of Exercising Option**.

(a) In order to exercise this option with respect to all or any part of the Option Shares for which this option is at the time exercisable, Participant (or any other person or persons exercising the option) must take the following actions:

(i) Execute and deliver to the Company a Notice of Exercise for the Option Shares for which the option is exercised.

(ii) Pay the aggregate Option Price for the purchased Shares in one or more of the following forms:

(A) cash or check made payable to the Company;

(B) Shares held by Participant (or any other person or persons exercising the option) for the requisite period necessary to avoid a charge to the Company's earnings for financial reporting purposes and valued at Fair Market Value on the Exercise Date; or

(C) provided that no restrictions against trading in the Shares are then in effect, as contemplated by Paragraph 11, (I) through a “net exercise” arrangement to the extent permitted by applicable law, or (II) through a special sale and remittance procedure pursuant to which Participant (or any other person or persons exercising the option) shall concurrently provide irrevocable instructions (x) to a Company-approved brokerage firm to effect the immediate sale of the purchased Shares and remit to the Company, out of the sale proceeds available on the settlement date, sufficient funds to cover the aggregate Option Price payable for the purchased Shares plus all applicable income and employment taxes required to be withheld by the Company by reason of such exercise and (y) to the Company to deliver the certificates for or other evidence of the purchased Shares directly to such brokerage firm in order to complete the sale.

Except to the extent the net exercise or the sale and remittance procedure is utilized in connection with the option exercise, payment of the Option Price must accompany the Notice of Exercise delivered to the Company in connection with the option exercise.

(iii) Furnish to the Company appropriate documentation that the person or persons exercising the option (if other than Participant) have the right to exercise this option.

(iv) Make appropriate arrangements with the Company (or Parent or Subsidiary employing or retaining Participant) for the satisfaction of all income and employment tax withholding requirements applicable to the option exercise.

(b) As soon as practical after the Exercise Date, the Company shall deliver to or on behalf of Participant (or any other person or persons exercising this option) a certificate for the purchased Option Shares, with the appropriate legends affixed thereto, shall effect book-entry registration in the Participant's (or such other person's) name.

(c) In no event may this option be exercised for any fractional shares.

11. **Compliance with Laws and Regulations**.

(a) The exercise of this option and the delivery of the Shares upon such exercise shall be subject to compliance by the Company and Participant with all applicable requirements of law relating thereto and with all applicable regulations of any stock exchange on which the Shares may be listed for trading at the time of such exercise and delivery.

(b) The inability of the Company to obtain approval from any regulatory body having authority deemed by the Company to be necessary to the lawful issuance or delivery and sale of any Shares pursuant to this option shall relieve the Company of any liability with respect to the non-issuance, non-delivery or sale of the Shares as to which such approval shall not have been obtained. The Company, however, shall use its best efforts to obtain all such approvals.

12. **Successors and Assigns**. Except to the extent otherwise provided in Paragraphs 3 and 6, the provisions of this Award Agreement shall inure to the benefit of, and be binding upon, the Company and its successors and assigns and Participant and Participant's assigns and Beneficiaries.

13. **Notices**. Any notice required to be given or delivered to the Company under the terms of this Award Agreement shall be in writing and addressed to the Company at its principal corporate offices. Any notice required to be given or delivered to Participant shall be in writing and addressed to Participant at the address indicated below Participant's signature line on the Notice of Grant. All notices shall be deemed effective upon personal delivery or upon deposit in the U.S. mail, postage prepaid and properly addressed to the party to be notified.

14. **Construction**. This Award Agreement and the option evidenced hereby are made and granted pursuant to the Plan and are in all respects limited by and subject to the terms of the Plan. All decisions of the Committee with respect to any question or issue arising under the Plan or this Award Agreement shall be conclusive and binding on all persons having an interest in this option.

15. **Governing Law**. The interpretation, performance and enforcement of this Award Agreement shall be governed by the laws of the State of Delaware without resort to that State's conflict-of-laws rules.

16. **Excess Shares**. If the Option Shares covered by this Award Agreement exceed, as of the Award Date, the number of Shares which may without stockholder approval be delivered under the Plan, then this option shall be void with respect to those excess Shares, unless stockholder approval of an amendment sufficiently increasing the number of Shares issuable under the Plan is obtained in accordance with the provisions of the Plan.

17. **Additional Terms Applicable to an Incentive Stock Option**. The terms of any Incentive Stock Option granted under the Plan shall be designed to comply in all respects with the provisions of Section 422 of the Code, or any successor provision thereto, and any regulations promulgated thereunder. Notwithstanding anything in this Paragraph 17 to the contrary, Options designated as Incentive Stock Options shall not be eligible for treatment under the Code as Incentive Stock Options (and will be deemed to be Non-Qualified Stock Options) to the extent that either (1) the aggregate Fair Market Value of Shares (determined as of the time of grant) with respect to which such Options are exercisable for the first time by Participant during any calendar year (under all plans of the Company and any Subsidiary) exceeds $100,000, taking Options into account in the order in which they were granted, or (2) such Options otherwise remain exercisable but are not exercised within three (3) months of termination of employment (or such other period of time provided in Section 422 of the Code).

18. **Leave of Absence**. The following provisions shall apply upon Participant's commencement of an authorized leave of absence:

(a) The exercise schedule in effect under the Notice of Grant shall be frozen as of the first day of the authorized leave, and this option shall not become exercisable for any additional installments of the Option Shares during the period Participant remains on such leave.

(b) Should Participant resume active Employee status within sixty (60) days after the start date of the authorized leave, Participant shall, for purposes of the exercise schedule set forth in the Notice of Grant, receive Service credit for the entire period of such leave. If Participant does not resume active Employee status within such sixty (60)-day period, then no Service credit shall be given for the period of such leave.

(c) If this option is designated as an Incentive Stock Option in the Notice of Grant, then the following additional provision shall apply:

(i) If the leave of absence continues for more than ninety (90) days, then this option shall automatically convert to a Non-Qualified Stock Option at the end of the three (3)-month period measured from the ninety-first (91st) day of such leave, unless Participant's reemployment rights are guaranteed by statute or by written agreement. Following any such conversion of this option, all subsequent exercises of this option, whether effected before or after Participant's return to active Employee status, shall result in an immediate taxable event, and the Company shall be required to collect from Participant the income and employment withholding taxes applicable to such exercise.

(ii) In no event shall this option become exercisable for any additional Option Shares or otherwise remain outstanding if Participant does not resume Employee status prior to the Expiration Date.

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EXHIBIT I
NOTICE OF EXERCISE

I hereby notify Discovery Laboratories, Inc. (the "Company") that I elect to purchase _____ Shares (the "Purchased Shares") at the Option Price of $ _____ per share pursuant to that certain option (the "Option") granted to me under the Company's 2011 Long-Term Incentive Plan on _____, ____.

Concurrently with the delivery of this Exercise Notice to the Company, I shall hereby pay to the Company the Option Price for the Purchased Shares in accordance with the provisions of my Notice of Grant and Award Agreement with the Company (or other documents) evidencing the Option and shall deliver whatever additional documents may be required by such agreement as a condition for exercise. Alternatively, if I am eligible I may utilize the net exercise or the special broker-dealer sale and remittance procedure specified in my agreement to effect payment of the Option Price.

_____
Date

_____
Participant

Address: _____

_____

Print name in exact manner it is to appear on the stock certificate: _____

Address to which certificate is to be sent, if different from address above: _____

_____

Social Security Number: _____

Employee Number: _____

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APPENDIX

The following definitions shall be in effect under the Award Agreement:

Award Date shall mean the effective date of grant of the option as specified in the Notice of Grant.

Award Agreement shall mean this Stock Option Agreement and the associated Notice of Grant pursuant to which the Option is granted.

Beneficiary shall mean, in the event the Committee implements a beneficiary designation procedure, the person designated by Participant, pursuant to such procedure, to succeed to such person's rights under any outstanding awards held by Participant at the time of death. In the absence of such procedure or designation, the Beneficiary shall be Participant's personal representative or the person or persons to whom this Option is transferred by will or the laws of descent and distribution.

Board shall mean the Company's Board of Directors.

Cause, with respect to any Employee or Consultant of the Company or a Subsidiary, shall have the meaning set forth in such person's employment, consulting or other applicable agreement, or, in the absence of any such agreement or if such term is not defined in any such agreement, shall mean any one or more of the following, as determined by the Committee:

(i) willful misconduct or gross negligence in the performance of such person's duties;

(ii) willful and continued failure or refusal to perform satisfactorily any duties reasonably requested in the course of such person's employment by, or service to, the Company (other than a failure resulting from such person's disability); or

(iii) fraudulent, dishonest or other improper conduct engaged in by such person that causes, or has the potential to cause, harm to the Company or any of its Subsidiaries, or its or their business or reputation, including, without limitation, such person's violation of any policies of the Company applicable to the such person, such person's violation of laws, rules or regulations applicable to such person, criminal activity, habitual drunkenness or use of illegal drugs.

Change in Control shall have the meaning, if any, set forth in a Participant's employment, consulting or other applicable agreement, or, if such term is not defined in any such agreement, shall mean the first to occur of the following:

(i) any Person (other than (1) the Company, or (2) any trustee or other fiduciary under an employee benefit plan of the Company), is or becomes the beneficial owner (as defined in Rule 13d-3 under the 1934 Act), directly or indirectly, of securities of the Participant's Employer (as defined below) by reason of having acquired such securities during the 12-month period ending on the date of the most recent acquisition (not including any securities acquired directly from the Company or its Affiliates) representing thirty percent (30%) or more of the total voting power of the Participant's Employer's then outstanding voting securities;

(ii) the majority of members of the board of directors of the Participant's Employer is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the board of directors of the Participant's Employer before the date of the appointment;

(iii) there is consummated a merger or consolidation of the Participant's Employer or any subsidiary thereof with any other corporation or other entity, resulting in a change described in clauses (i), (ii), (iv) or (v) of this definition, other than (1) a merger or consolidation that would result in the voting securities of the Participant's Employer outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving or parent entity) more than sixty percent (60%) of the total voting power of the voting securities of the Participant's Employer or such surviving or parent entity outstanding immediately after such merger or consolidation or (2) a merger or consolidation effected to implement a recapitalization of the Company or the Participant's Employer (or similar transaction) in which no Person, directly or indirectly, acquired forty percent (40%) or more of the total voting power of the then outstanding securities of the Participant's Employer (not including any securities acquired directly from the Company or its Affiliates);

(iv) a liquidation of the Participant's Employer involving the sale to any Person of at least forty percent (40%) of the total gross fair market value of all of the assets of the Participant's Employer immediately before the liquidation; or

(v) the sale or disposition by the Participant's Employer or any direct or indirect subsidiary of the Participant's Employer to any Person (other than any Subsidiary) of assets that have a total fair market value equal to forty percent (40%) or more of the total gross fair market value of all of the assets of the Participant's Employer and its subsidiaries (taken as a whole) immediately before such sale or disposition (or any transaction or related series of transactions having a similar effect), other than a sale or disposition by the Company or the Participant's Employer or any direct or indirect subsidiary of either to an entity at least sixty percent (60%) of the total voting power of the voting securities of which is beneficially owned by Stockholders of the Company or the Participant's Employer in substantially the same proportions as their beneficial ownership of the Company or the Participant's Employer immediately prior to such sale.

For purposes of this definition, "Participant's Employer" shall mean (1) the Company or a Subsidiary corporation for which the Participant directly provides services or (2) a corporation that is a majority stockholder of the Company or a Subsidiary, or any corporation in a chain of corporations each of which is a majority stockholder of another corporation in the chain, ending with the corporation described in (1).

Code shall mean the Internal Revenue Code of 1986, as a mended from time to time. A reference to a section of the Code shall be deemed to include any successor sections of the Code.

Committee shall mean a committee of the Board, acting in accordance with the provisions of Section 3 of the Plan, designated by the Board to administer the Plan. To the extent the Committee has delegated authority, the term "Committee" shall refer to such delegate.

Company shall mean Discovery Laboratories, Inc. and any Subsidiary to which Participant may render Services.

Disability for each respective Participant shall have the meaning set forth in the Participant's employment agreement; provided, that if such term is not defined in any such agreement then "Disability" shall mean (i) with respect to any Incentive Stock Option, a permanent and total disability, within the meaning of Section 22(e)(3) of the Code, and (ii) for any other purpose, "disability" as defined in the Company's long term disability program applicable to the Participant (or that would be applicable to the Participant if the Participant elected coverage).

Employee shall mean any person treated as an employee (including officers and directors) in the records of the Company or any Subsidiary and who is subject to the control and direction of the Company or any Subsidiary with regard to both the work to be performed and the manner and method of performance.

Exercise Date shall mean the date on which the option shall have been exercised in accordance with Paragraph 10 of this Award Agreement.

Expiration Date shall mean the date on which the option expires as specified in the Notice of Grant.

Fair Market Value of a Share on any date of reference shall be determined by the Committee, in its sole discretion, and may be different for different purposes. Unless the Committee determines otherwise,

(i) if the Shares are listed or admitted for trading on any United States national securities exchange, or if actual transactions are otherwise reported on a consolidated transaction reporting system, the last reported sale price of a Share on such exchange or reporting system, as reported in any newspaper of general circulation, or

(ii) if clause (i) is not applicable, the mean of the high bid and low asked quotations for a Share as reported by the National Quotation Bureau, Incorporated if at least two securities dealers have inserted both bid and asked quotations for the Shares on at least five of the 10 preceding trading days; or

(iii) if clauses (i) and (ii) above are not applicable to the Company (e.g., if the Shares are not then publicly traded or quoted), then the "Fair Market Value" of a Share shall be the fair market value (i.e., the price at which a willing seller would sell a Share to a willing buyer when neither is acting under compulsion and when both have reasonable knowledge of all relevant facts) of a Share on such date as the Committee in its sole and absolute discretion shall determine in a fair and uniform manner.

Incentive Stock Option shall mean an option that is intended to meet the requirements of Section 422 of the Code.

Non-Qualified Stock Option shall mean an option granted under this Award Agreement that is not intended to be an Incentive Stock Option.

Notice of Exercise shall mean the notice of exercise in the form attached hereto as Exhibit I.

Notice of Grant shall mean the Notice of Grant of Stock Options accompanying the Award Agreement, pursuant to which Participant has been informed of the basic terms of the option evidenced hereby.

Option Price shall mean the purchase price payable for Option Shares under this option, as specified in the Notice of Grant.

Option Shares shall mean the number of Shares subject to the option as specified in the Notice of Grant.

Participant shall mean the person to whom the option is granted as specified in the Notice of Grant.

Performance Criteria shall mean any quantitative and/or qualitative measures, as determined by the Committee, which may be used to measure the level of performance of the Company or any individual Participant during a Performance Period, including any Qualifying Performance Criteria.
[Delete unless option is performance-vested]

Performance Period shall mean any period as determined by the Committee in its sole discretion.
[Delete unless option is performance-vested]

Plan shall mean the Company's 2011 Long-Term Incentive Plan, as amended from time to time.

Qualifying Performance Criteria shall mean one or more of the following performance criteria, either individually, alternatively or in any combination, applied to either the Company as a whole or to a business unit or related Subsidiary, and measured either annually or cumulatively over a period of years, on an absolute basis or relative to a pre-established target, to a previous year's results or to a designated comparison group, in each case as specified by the Committee in the Award Agreement: achieving specified milestones in the discovery and development, commercialization or manufacturing of one or more of the Company product candidates, obtaining debt or equity financing, achieving personal management objectives, achieving sales, revenue, net income (before or after taxes), net earnings, earnings per share, return on total capital, return on equity, cash flow, cash flow from operations, operating profit and/or margin rate targets, subject to adjustment by the Committee to remove the effect of charges for restructurings, discontinued operations, extraordinary items and all items of gain, loss or expense determined to be extraordinary or unusual in nature or infrequent in occurrence, related to the disposal of a segment or a business, or related to a change in accounting principle or otherwise.
[Delete unless option is performance-vested]

Service shall mean Participant's performance of services for the Company (or any Subsidiary) in the capacity of Employee, non-employee director or consultant.

Shares shall mean the common shares of the Company and such other securities as may become the subject of this Option pursuant to an adjustment made under Section 4(b) of the Plan.

Subsidiary shall mean a subsidiary company as defined in Section 424(f) of the Code (with the Company being treated as the employer corporation for purposes of this definition).

EXHIBIT 10.3

DISCOVERY LABORATORIES, INC.
2011 LONG-TERM INCENTIVE PLAN
STOCK OPTION AGREEMENT

Non-Employee Director

RECITALS

A. The Board has adopted the Discovery Laboratories, Inc. 2011 Long-Term Incentive Plan (the "Plan") for the purpose of encouraging selected Employees, Directors and Consultants of the Company and its Subsidiaries to acquire a proprietary interest in the growth and performance of the Company, to generate an increased incentive to contribute to the Company's future success and prosperity, thus enhancing the value of the Company for the benefit of its stockholders, and to enhance the ability of the Company and its Subsidiaries to attract and retain exceptionally qualified individuals upon whom, in large measure, the sustained progress, growth and profitability of the Company depend.

Participant is a non-employee Director who will render valuable Services to the Company, and this Award Agreement is executed pursuant to, and is intended to carry out the purposes of, the Plan in connection with the Company's grant of an option to Participant.

B. All capitalized terms in this Stock Option Agreement ("Award Agreement") shall have the meaning assigned to them in the Plan. For convenience, relevant portions of certain of the Plan definitions and certain additional definitions relating to this Award Agreement are included in the attached Appendix. This Award Agreement including, the Notice of Grant, is subject to the terms of the Plan, which are incorporated in this Award Agreement by reference. If there is a conflict between the terms of the Plan and this Award Agreement or the Notice of Grant, the terms of the Plan shall prevail.

NOW, THEREFORE, it is hereby agreed as follows:

1. **Award of Option**. The Company hereby grants to Participant, as of the Award Date, an option to purchase up to the number of Option Shares specified in the Notice of Grant. The Option Shares shall be purchasable from time to time as specified in Paragraph 4 during the option term specified in Paragraph 2 at the Option Price set forth on the Notice of Grant.

2. **Option Term**. This option shall have a term commencing on the Award Date and ending on the Expiration Date set forth on the Notice of Grant. The option shall expire at the close of business on the Expiration Date, unless sooner terminated in accordance with Paragraph 5 or 6.

3. **Limited Transferability**. The option granted under this Award Agreement shall not be assignable, alienable, saleable, or transferable by Participant other than by will or by the laws of descent and distribution; provided, however, that, if a procedure shall be adopted by the Committee at any time, Participant may designate a beneficiary or beneficiaries to exercise the rights of Participant with respect to this option upon Participant's death. The option granted under this Award Agreement shall be exercisable during Participant's lifetime only by Participant or, if permissible under applicable law, by Participant's guardian or legal representative. This option may not be pledged, alienated, attached, or otherwise encumbered, and any purported pledge, alienation, attachment, or encumbrance thereof shall be void and unenforceable against the Company or any affiliate of the Company. Notwithstanding the foregoing, this option may, in connection with Participant's estate plan, be assigned, in whole or in part, during Participant's lifetime to one or more members of Participant's immediate family or to a trust established for the exclusive benefit of one or more such family members. The assigned portion shall be exercisable only by the person or persons who acquire a proprietary interest in the option pursuant to such assignment. The terms applicable to the assigned portion shall be the same as those in effect for this option immediately prior to such assignment and shall be set forth in such documents issued to the assignee as the Committee may deem appropriate.

4. **Dates of Exercise**. This option shall vest and become exercisable for the Option Shares in one or more installments as specified in the Notice of Grant. As the option becomes exercisable for such installments, those installments shall accumulate, and the option shall remain exercisable for the accumulated installments until the Expiration Date or sooner termination of the option term under Paragraph 5 or 6.

5. **Termination of Service**. The option term and this option shall expire and cease to be exercisable if the Participant's Service as a non-employee Director ceases prior to the Expiration Date pursuant to whichever of the following provisions becomes applicable:

(a) This option may not be exercised in the aggregate after termination of Service as a non-employee Director for more than the number of vested Option Shares for which this option was exercisable at the time of the Participant's cessation of Service as a non-employee Director, except as provided in Section 5(b). This option shall, immediately upon the Participant's cessation of Service as a non-employee director for any reason other than death or Disability, terminate and cease to be outstanding to the extent the Option is not otherwise at that time exercisable for vested Option Shares.

(b) Should the Participant cease Service as a non-employee Director by reason of death or Disability, then vesting under this option shall accelerate and this option shall become exercisable with respect to the total number of Option Shares and may be exercised by the Participant (or the Participant's Beneficiary as applicable) for any or all of those Option Shares until the earlier of (A) one (1) year after cessation as non-employee Director or (B) the Expiration Date.

6. **Special Acceleration of Option**. In the event of a Change in Control, but subject to the occurrence of the Change in Control, vesting under this option shall automatically accelerate so that, immediately prior to the effective date of the Change in Control, this option shall become exercisable with respect to the total number of Option Shares at the time subject to this option and may be exercised for any or all of those Option Shares. Notwithstanding the foregoing, the Committee shall have the discretion exercisable at any time during the option term to provide that such accelerated vesting shall not occur if the option is assumed by the successor corporation in the Change in Control.

This Award Agreement shall not in any way affect the right of the Company to adjust, reclassify, reorganize or otherwise change its capital or business structure or to merge, consolidate, dissolve, liquidate or sell or transfer all or any part of its business or assets.

7. **Repurchase Right.** If at any time Participant's Service as a non-employee Director is terminated for cause as determined by the Board in its sole discretion, or if Participant shall breach any covenants set forth in any written agreement between Participant and the Company, or the Company may, in its discretion, for a period of one (1) year after the termination for cause or upon the actual discovery by the Company of the breach, as the case may be, and upon 10 (ten) days' notice to Participant, (i) repurchase all or any portion of any Shares acquired by Participant upon Participant's exercise of this option, and/or (ii) require Participant to repay to the Company the amount of any profits realized by Participant upon the sale or other disposition during the preceding three (3) years of any Shares acquired by Participant upon Participant's exercise of this option. The purchase price for any Shares repurchased by the Company pursuant to clause (i) of this Paragraph shall be the lesser of the price paid by Participant to acquire such Shares and the Fair Market Value thereof on the date of such purchase by the Company. In addition, the Company shall have repurchase rights in accordance with the terms of any repurchase policy as in effect from time to time.

8. **Adjustment in Option Shares**. Should any change be made to the Shares by reason of any stock split, stock dividend, recapitalization, combination of shares, exchange of shares or other change affecting the outstanding Shares as a class without the Company's receipt of consideration, appropriate adjustments shall be made to (i) the total number and/or class of securities subject to this option and (ii) the Option Price in order to reflect such change and thereby preclude a dilution or enlargement of benefits hereunder.

9. **Stockholder Rights**. The holder of this option shall not have any stockholder rights with respect to the Option Shares until such person shall have exercised the option, paid the Option Price and become a holder of record of the purchased Shares.

10. **Manner of Exercising Option**.

(a) In order to exercise this option with respect to all or any part of the Option Shares for which this option is at the time exercisable, Participant (or any other person or persons exercising the option) must take the following actions:

(i) Execute and deliver to the Company a Notice of Exercise for the Option Shares for which the option is exercised.

(ii) Pay the aggregate Option Price for the purchased Shares in one or more of the following forms:

(A) cash or check made payable to the Company;

(B) Shares held by Participant (or any other person or persons exercising the option) for the requisite period necessary to avoid a charge to the Company's earnings for financial reporting purposes and valued at Fair Market Value on the Exercise Date; or

(C) provided that no restrictions against trading in the Shares are then in effect, as contemplated by Paragraph 11, (I) through a “net exercise” arrangement to the extent permitted by applicable law, or (II) through a special sale and remittance procedure pursuant to which Participant (or any other person or persons exercising the option) shall concurrently provide irrevocable instructions (x) to a Company-approved brokerage firm to effect the immediate sale of the purchased Shares and remit to the Company, out of the sale proceeds available on the settlement date, sufficient funds to cover the aggregate Option Price payable for the purchased Shares, and (y) to the Company to deliver the certificates for or other evidence of the purchased Shares directly to such brokerage firm in order to complete the sale.

Except to the extent the net exercise or the sale and remittance procedure is utilized in connection with the option exercise, payment of the Option Price must accompany the Notice of Exercise delivered to the Company in connection with the option exercise.

(iii) Furnish to the Company appropriate documentation that the person or persons exercising the option (if other than Participant) have the right to exercise this option.

(b) As soon as practical after the Exercise Date, the Company shall deliver to or on behalf of Participant (or any other person or persons exercising this option) a certificate for the purchased Option Shares, with the appropriate legends affixed thereto or shall effect book-entry registration in the Participant's (or such other person's) name.

(c) In no event may this option be exercised for any fractional shares.

11. **Compliance with Laws and Regulations**.

(a) The exercise of this option and the delivery of the Shares upon such exercise shall be subject to compliance by the Company and Participant with all applicable requirements of law relating thereto and with all applicable regulations of any stock exchange on which the Shares may be listed for trading at the time of such exercise and delivery.

(b) The inability of the Company to obtain approval from any regulatory body having authority deemed by the Company to be necessary to the lawful issuance or delivery and sale of any Shares pursuant to this option shall relieve the Company of any liability with respect to the non-issuance, non-delivery, or sale of the Shares as to which such approval shall not have been obtained. The Company, however, shall use its best efforts to obtain all such approvals.

12. **Successors and Assigns**. Except to the extent otherwise provided in Paragraphs 3 and 6, the provisions of this Award Agreement shall inure to the benefit of, and be binding upon, the Company and its successors and assigns and Participant and Participant's assigns and Beneficiaries.

13. **Notices**. Any notice required to be given or delivered to the Company under the terms of this Award Agreement shall be in writing and addressed to the Company at its principal corporate offices. Any notice required to be given or delivered to Participant shall be in writing and addressed to Participant at the address indicated below Participant's signature line on the Notice of Grant. All notices shall be deemed effective upon personal delivery or upon deposit in the U.S. mail, postage prepaid and properly addressed to the party to be notified.

14. **Construction**. This Award Agreement and the option evidenced hereby are made and granted pursuant to the Plan and are in all respects limited by and subject to the terms of the Plan. All decisions of the Committee with respect to any question or issue arising under the Plan or this Award Agreement shall be conclusive and binding on all persons having an interest in this option.

15. **Governing Law**. The interpretation, performance and enforcement of this Award Agreement shall be governed by the laws of the State of Delaware without resort to that State's conflict-of-laws rules.

16. **Excess Shares**. If the Option Shares covered by this Award Agreement exceed, as of the Award Date, the number of Shares which may without stockholder approval be delivered under the Plan, then this option shall be void with respect to those excess Shares, unless stockholder approval of an amendment sufficiently increasing the number of Shares issuable under the Plan is obtained in accordance with the provisions of the Plan.

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EXHIBIT I
NOTICE OF EXERCISE

I hereby notify Discovery Laboratories, Inc. (the "Company") that I elect to purchase _____Shares (the "Purchased Shares") at the Option Price of $ _____ per Share pursuant to that certain option (the "Option") granted to me under the Company's 2011 Long-Term Stock Incentive Plan on _____, ___.

Concurrently with the delivery of this Exercise Notice to the Company, I shall hereby pay to the Company the Option Price for the Purchased Shares in accordance with the provisions of my Notice of Grant and Award Agreement with the Company (or other documents) evidencing the Option and shall deliver whatever additional documents may be required by such agreement as a condition for exercise. Alternatively, if I am eligible I may utilize the net exercise or the special broker-dealer sale and remittance procedure specified in my agreement to effect payment of the Option Price.

Date

Participant

Address:

Print name in exact manner it is to appear on the stock certificate:

Address to which certificate is to be sent, if different from address above:

Social Security Number:

Employee Number:

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APPENDIX

The following definitions shall be in effect under the Award Agreement:

Award Agreement shall mean this Stock Option Agreement.

Award Date shall mean the effective date of grant of the option as specified in the Notice of Grant.

Beneficiary shall mean, in the event the Committee implements a beneficiary designation procedure, the person designated by Participant, pursuant to such procedure, to succeed to such person's rights under any outstanding awards held by Participant at the time of death. In the absence of such procedure or designation, the Beneficiary shall be Participant's personal representative or the person or persons to whom the Award is transferred by will or the laws of descent and distribution.

Board shall mean the Company's Board of Directors.

Change in Control means the first to occur of the following:

(i) any Person (other than (1) the Company, or (2) any trustee or other fiduciary under an employee benefit plan of the Company), is or becomes the beneficial owner (as defined in Rule 13d-3 under the 1934 Act), directly or indirectly, of securities of the Participant's Employer (as defined below) by reason of having acquired such securities during the 12-month period ending on the date of the most recent acquisition (not including any securities acquired directly from the Company or its Affiliates) representing thirty percent (30%) or more of the total voting power of the Company's then outstanding voting securities;

(ii) the majority of members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment;

(iii) there is consummated a merger or consolidation of the Company or any subsidiary thereof with any other corporation or other entity, resulting in a change described in clauses (i), (ii), (iv) or (v) of this definition, other than (1) a merger or consolidation that would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving or parent entity) more than sixty percent (60%) of the total voting power of the voting securities of the Company or such surviving or parent entity outstanding immediately after such merger or consolidation or (2) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person, directly or indirectly, acquired forty percent (40%) or more of the total voting power of the then outstanding securities of the Company (not including any securities acquired directly from the Company or its Affiliates);

(iv) a liquidation of the Company involving the sale to any Person of at least forty percent (40%) of the total gross fair market value of all of the assets of the Company immediately before the liquidation; or

(v) the sale or disposition by the Company or any direct or indirect subsidiary of the Company to any Person (other than any Subsidiary) of assets that have a total fair market value equal to forty percent (40%) or more of the total gross fair market value of all of the assets of the Company and its subsidiaries (taken as a whole) immediately before such sale or disposition (or any transaction or related series of transactions having a similar effect), other than a sale or disposition by the Company or any direct or indirect subsidiary thereof to an entity at least sixty percent (60%) of the total voting power of the voting securities of which is beneficially owned by stockholder of the Company in substantially the same proportions as their beneficial ownership of the Company immediately prior to such sale.

Code shall mean the Internal Revenue Code of 1986, as amended from time to time. A reference to a section of the Code shall be deemed to include any successor sections of the Code.

Committee shall mean a committee of the Board, acting in accordance with the provisions of Section 3 of the Plan, designated by the Board to administer the Plan. To the extent the Committee has delegated authority, the term "Committee" shall refer to such delegate.

Company shall mean Discovery Laboratories, Inc.

Director shall mean a member of the Board.

Disability shall mean a physical or mental disability of the Participant as determined by the Committee, based on such medical evidence as the Committee deems appropriate.

Exercise Date shall mean the date on which the option shall have been exercised in accordance with Paragraph 10 of this Award Agreement.

Expiration Date shall mean the date on which the option expires as specified in the Notice of Grant.

Fair Market Value of a Share on any date of reference shall be determined by the Committee, in its sole discretion, and may be different for different purposes. Unless the Committee determines otherwise,

(i) if the Shares are listed or admitted for trading on any United States national securities exchange, or if actual transactions are otherwise reported on a consolidated transaction reporting system, the last reported sale price of a Share on such exchange or reporting system, as reported in any newspaper of general circulation, or

(ii) if clause (i) is not applicable, the mean of the high bid and low asked quotations for a Share as reported by the National Quotation Bureau, Incorporated if at least two securities dealers have inserted both bid and asked quotations for the Shares on at least five of the 10 preceding trading days; or

(iii) if clauses (i) and (ii) are not applicable to the Company (e.g., if the Shares are not then publicly traded or quoted), then the "Fair Market Value" of a Share shall be the fair market value (i.e., the price at which a willing seller would sell a Share to a willing buyer when neither is acting under compulsion and when both have reasonable knowledge of all relevant facts) of a Share on such date as the Committee in its sole and absolute discretion shall determine in a fair and uniform manner.

Notice of Exercise shall mean the notice of exercise in the form attached hereto as Exhibit I.

Notice of Grant shall mean the Notice of Grant of Stock Options accompanying the Award Agreement, pursuant to which Participant has been informed of the basic terms of the option evidenced hereby.

Option Price shall mean the purchase price payable for Option Shares under this option, as specified in the Notice of Grant.

Option Shares shall mean the number of Shares subject to the option as specified in the Notice of Grant.

Participant shall mean the Director to whom the option is granted as specified in the Notice of Grant.

Plan shall mean the Company's 2011 Long-Term Incentive Plan, as amended from time to time.

Service shall mean Participant's performance of services for the Company in the capacity of non-employee Director.

Shares shall mean the common shares of the Company and such other securities as may become the subject of Awards pursuant to an adjustment made under Section 4(b) of the Plan.

Subsidiary shall mean a subsidiary company as defined in Section 424(f) of the Code (with the Company being treated as the employer corporation for purposes of this definition).

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: May 15, 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: May 15, 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 March 31, 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: May 15, 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.