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

FORM 10-Q

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

For the quarterly period ended March 31, 2013

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

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

As of April 30, 2013, 43,764,737 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 inactive subsidiary, Acute Therapeutics, Inc.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans and our expectations and timing related to commercialization of SURFAXIN®, the AFECTAIR® device for infants and our products under development, if approved; our expectations, timing and outcomes of submitting regulatory filings for our products under development; our research and development programs, including planning and development activities, anticipated timing of clinical trials and potential development milestones, for our KL_4 surfactant pipeline, our capillary aerosol generator (CAG) and aerosol-conducting airway connectors for delivery of aerosolized medications; plans for the manufacture of drug products and medical devices, including active pharmaceutical ingredients and materials thereof, 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 risks that we will require, but may be unable to secure, additional capital to continue our operations, fund our debt service and support our research and development activities, which risks are amplified by a recent delay in the anticipated commercial availability of SURFAXIN from the second quarter to the fourth quarter of 2012;

- the risks that the delay in anticipated commercial availability of SURFAXIN from the second quarter to the fourth quarter of 2012 could adversely impact our plans and our ability to meet our objectives, and any further delay could have a material adverse effect on our business, operations and financial condition;

- the risk that, although we plan to pace certain other investments that we otherwise would have made during this delay, our plan to maintain our commercial and medical affairs capabilities and continue to invest in the AEROSURF® development program, will limit our ability to significantly reduce our cash outflows;

- The risks that, while we expect to prepare and file by early June 2013 a response to the United States (U.S.) Food and Drug Administration’s (FDA) response to our recent submission related to our improved analytical chemistry method and updated SURFAXIN product specifications, and we expect that the FDA will respond within four months thereafter, we may be unable to file our response within the anticipated time line or the FDA may not respond as anticipated or may not agree with our submission, which could prevent our proceeding with the commercial introduction of SURFAXIN as planned, if ever; and that, if the recent delay extends beyond December 31, 2013, our ability to access the $20 million under the Deerfield Facility will expire, which could have a material adverse effect on our ability to fund our operations;

- the risk that, even if we are able to gain FDA confirmation of the recently-submitted updated SURFAXIN product specifications within our anticipated time, we nevertheless will require, but may be unable to secure, significant additional capital to fund our operations and our research and development activities, including our planned clinical programs, until our revenues are sufficient to offset our cash outflows, if ever. To the extent that we raise such capital through additional financings, such additional financings could result in equity dilution. Moreover, we have pledged substantially all of our assets to secure our obligations under the Deerfield Facility, which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investments;

- the risk that if we are unable for any reason to introduce, or if there is a significant further delay in the commercial introduction of, SURFAXIN in the U.S. and other markets as planned, or if we do not achieve the level of expected revenues that we have forecasted for SURFAXIN and AFECTAIR, we may be unable to secure additional capital when needed, whether from new strategic alliances or other sources, to sustain our operations, which could have a material adverse effect on our ability to continue investments in our commercial and medical affairs activities, as well as our research and development programs and operations;

- 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 ultimately could have a material adverse effect on our business, financial condition and results of operations;

- the risk that we may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us in markets outside the U.S. with the development of our KL4 surfactant pipeline products, beginning with AEROSURF (a drug/device combination product based on our aerosolized KL4 surfactant and our CAG technology), and including the development of our lyophilized (freeze-dried) KL4 surfactant, and, if approved, commercialization of AEROSURF in markets outside the U.S.; and support the commercialization of SURFAXIN and, if approved, SURFAXIN LS™, our lyophilized dosage form of SURFAXIN, in countries where regulatory marketing authorization is facilitated by the information contained in the SURFAXIN new drug application (NDA) approved by the FDA; and potentially support the development of SURFAXIN LS;

- risks relating to the ability of our sales and marketing organization to effectively market SURFAXIN and AFECTAIR in the U.S., 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 plans to secure marketing and distribution capabilities in certain markets 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;

- risks relating to our ability to manage our growth effectively and timely modify our business strategy as needed to respond to developments in our commercial operations and research and development activities, as well as our business, our industry and other factors;

- risks relating to our ability to manufacture our KL_4 surfactant, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for both commercial and research and development activities;

- the risk that we, our contract manufacturer organizations (CMOs) or any of our third-party suppliers, many of which are single-source providers, may encounter problems or delays in manufacturing our KL_4 surfactant drug products, related substances used in the manufacture of our drug product, AFECTAIR aerosol-conducting airway connectors and related componentry, CAG devices and other materials on a timely basis or in an amount sufficient to support the commercial introduction of SURFAXIN and the AFECTAIR device for infants, as well as our research and development activities for our other product candidates;

- risks relating to the transfer of our manufacturing technology to CMOs and assemblers;
- 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 U.S. and elsewhere, for our drug product and medical device candidates, including AEROSURF, a drug-device combination product that we are developing to address RDS in premature infants and our KL4 lyophilized surfactant that we expect will be the drug component of AEROSURF and potentially be developed as a life cycle extension of SURFAXIN under the name SURFAXIN LS; and AFECTAIR, our novel aerosol-conducting airway connectors;
- the risk that we and the FDA or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;
- risks relating to our research and development activities, which among other things involve time-consuming and expensive preclinical studies and other efforts, and potentially multiple clinical trials that may be subject to potentially significant delays or regulatory holds, or fail;
- risks relating to our ability to develop and manufacture drug-device combination products based on our KL4 surfactant and CAG technology for preclinical and clinical studies of our product candidates and, if approved, for commercialization;
- 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 ATM Program and Committed Equity Financing Facility (CEFF) 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 adjustments);

- 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 risk that we may become involved in securities, product liability and other litigation and that our insurance may be insufficient to cover costs of damages and defense;

- the risk that we will be unable to attract and retain key employees in a competitive market for skilled personnel, which could have a material adverse effect on our commercial, research and development activities and our operations;

- the risk that we or our strategic partners or collaborators will not be able to attract or retain qualified scientific, professional and other personnel, which could affect our ability to develop and market our products; and

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

Pharmaceutical, biotechnology and medical device 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 as 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, 2013 (Unaudited)	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,370	$ 26,892
Inventory	–	195
Prepaid expenses and other current assets	621	719
Total Current Assets	26,991	27,806
Property and equipment, net	1,660	1,737
Restricted cash	400	400
Other Assets	111	–
Total Assets	$ 29,162	$ 29,943
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,825	$ 1,166
Accrued expenses	4,974	4,159
Common stock warrant liability	6,143	6,305
Equipment loans and capitalized leases, current portion	70	69
Total Current Liabilities	13,012	11,699
Long-term debt, net of discount of $3,917 in 2013 and $0 in 2012	6,083	–
Equipment loans and capitalized leases, non-current portion	129	148
Other liabilities	481	443
Total Liabilities	19,705	12,290
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 100,000,000 shares authorized; 43,785,629 and 43,673,636 shares issued, 43,764,737 and 43,652,744 shares outstanding at March 31, 2013 and December 31, 2012, respectively	44	44
Additional paid-in capital	459,838	455,398
Accumulated deficit	(447,371)	(434,735)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total Stockholders' Equity	9,457	17,653
Total Liabilities & Stockholders' Equity	$ 29,162	$ 29,943

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

(in thousands, except per share data)

	Three Months Ended March 31,	
	2013	**2012**
Grant revenue	$ 72	$ –
Expenses:		
Research and development	8,472	4,533
Selling, general and administrative	4,220	2,047
	12,692	6,580
Operating loss	(12,620)	(6,580)
Change in fair value of common stock warrant liability	162	(3,434)
Other income / (expense):		
Interest and other income	1	2
Interest and other expense	(178)	(4)
Other income / (expense), net	(177)	(2)
Net loss	$ (12,635)	$ (10,016)
Net loss per common share –		
Basic and diluted	$ (0.29)	$ (0.37)
Weighted-average number of common shares outstanding – basic and diluted	43,657	27,162

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

(in thousands)

	Three Months Ended March 31,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$ (12,635)	$ (10,016)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	197	288
Stock-based compensation and 401(k) match	612	542
Fair value adjustment of common stock warrants	(162)	3,434
Amortization of discount on long-term debt	59	–
Changes in:		
Inventory	195	–
Prepaid expenses and other current assets	98	49
Accounts payable	659	228
Accrued expenses	814	(85)
Other assets	(111)	–
Other liabilities and accrued interest	39	14
Net cash used in operating activities	(10,235)	(5,546)
Cash flows from investing activities:		
Purchase of property and equipment	(120)	(138)
Net cash used in investing activities	(120)	(138)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt, net of expenses	9,850	–
Proceeds from exercise of common stock options	1	–
Proceeds from issuance of securities, net of expenses	–	43,604
Proceeds from exercise of common stock warrants	–	6,713
Repayment of equipment loans and capital lease obligations	(18)	(20)
Net cash provided by financing activities	9,833	50,297
Net (decrease) / increase in cash and cash equivalents	(522)	44,613
Cash and cash equivalents – beginning of period	26,892	10,189
Cash and cash equivalents – end of period	$ 26,370	$ 54,802
Supplementary disclosure of cash flows information:		
Interest paid	$ 116	$ 4

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 aerosolized drugs, including our aerosolized KL_4 surfactant, and other inhaled therapies. We believe that our proprietary technologies make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

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

In March 2012, the United States (U.S.) Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of 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. In the third quarter of 2012, during a routine review of our processes related to analytical testing and quality control of SURFAXIN drug product, we determined that one analytical chemistry method used to assess SURFAXIN drug product required improvement and that an update to SURFAXIN product specifications was needed. We promptly communicated with the FDA, improved and revalidated the analytical chemistry method, and submitted updated product specifications to the FDA. As a result, we estimated that the commercial availability of SURFAXIN drug product would be delayed until the second quarter 2013. We did not believe that the delay would have a material impact on our plans. However, in April 2013, the FDA requested information and provided recommendations intended to clarify certain aspects of the updated product specifications and our revalidated analytical chemistry method, including recommendations regarding how the product specifications should be documented and notated; a specific recommendation for the upper limit of a single product specification, which we can readily accept; a request for two existing documents related to the improved analytical chemistry method; and a request for supporting data from the improved and revalidated analytical chemistry method used on recent SURFAXIN batches. We believe that we will be able to respond to the FDA by early June. Based on the FDA's guidelines, which provide for four months for a review of our type of submission, we anticipate that, if we are successful and our submission is timely confirmed by the FDA, we will be able to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013. There can be no assurance, however, that the FDA will respond within the time line set forth in its guidelines or accept our proposed updated product specifications. Any extended delay in the commercial availability of SURFAXIN could have a material adverse effect on our ability to fund our operations and our development programs.

AEROSURF® is a drug/device combination product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). 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 frequently result in serious respiratory conditions and complications. Consequently, neonatologists generally will not treat infants who could benefit from surfactant therapy unless they determine that 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.

We are developing a lyophilized (freeze-dried) dosage form of our KL_4 surfactant that is stored as a powder and resuspended to liquid form prior to use with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are engaged in a technology transfer of our lyophilized KL_4 surfactant manufacturing process to a contract manufacturing organization (CMO) that has expertise in lyophilized products, and we expect that it will manufacture drug product for use in our preclinical and clinical development activities. This development plan is intended initially to support the use of our lyophilized KL_4 surfactant in our AEROSURF development program. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially in other major markets.

AFECTAIR® devices are our novel disposable aerosol-conducting airway connectors that simplify the delivery of aerosolized medications (including our aerosolized KL_4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. In February 2012, we registered our AFECTAIR device in the U.S. as a Class I, exempt medical device. Our initial device is AFECTAIR aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal or pediatric intensive care units (NICUs and PICUs, respectively). We are conducting a user experience program in select U.S. critical care centers representing approximately ten percent (10%) of our target institutions. This program is intended to facilitate peer-to-peer exchange among physicians and respiratory therapists and enable discussion about the potential advantages and proper utilization of this novel device, and is expected to be conducted through the first half of 2013. We believe that AFECTAIR aerosol-conducting airway connectors have the potential to become a new standard of care for the delivery of aerosolized medications and inhaled therapies to infants receiving aerosolized medication in the NICU and PICU.

We expect that we will be able to leverage the information, data and know-how that we gain from our development efforts with AEROSURF for RDS and the AFECTAIR device for infants to support development of a product pipeline intended to address serious critical care respiratory conditions of larger children and adults in PICUs and intensive care units (ICUs). However, we are delaying these efforts as we focus our resources on advancing the development of AEROSURF to phase 2 clinical trials and the commercial introduction of SURFAXIN and the AFECTAIR device for infants. If we are able to achieve these 2013 objectives, we believe we will be in a better position to assess the potential of developing products based on our CAG and aerosol-conductor airway connector technologies to address the critical care needs of patients in the PICU and ICU.

In the U.S., we have established our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in neonatal/pediatric respiratory critical care and will focus on neonatal indications, beginning with SURFAXIN and the AFECTAIR device for infants. These organizations will be primarily responsible to effect the commercial introduction of SURFAXIN. With our established relationships and contacts in the neonatal community, we believe that we also will be able to use our commercial and medical affairs organizations to effectively introduce the AFECTAIR device for infants in the U.S. We also expect that, in the future, these teams will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN and the AFECTAIR device for infants to efficiently support the introductions of AEROSURF and potentially SURFAXIN LS, if approved.

An important priority for us is to secure strategic and financial resources to support our operations and to advance our KL_4 surfactant and device development programs and the commercial introduction of our RDS products. We currently expect that the delay in commercial availability of SURFAXIN will most likely be for a period of up to six months and, accordingly, have decided to maintain our investments in commercial and medical affairs capabilities and development activities necessary to advance our AEROSURF development program potentially to initiate the planned phase 2 clinical program in the fourth quarter of 2013. We otherwise plan to slow the pace of our investments and manage our cash resources while we seek to secure the necessary capital from various potential sources, including debt and equity financings, strategic partnerships and collaboration arrangements and other transactions. The recent delay in the commercial availability of SURFAXIN has delayed access to a $20 million advance, which is payable upon the first commercial sale of SURFAXIN, under a loan facility (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield). If for any reason, we are unable to complete the first commercial sale of SURFAXIN by December 31, 2013, our ability to access the $20 million under the Deerfield Facility will expire. *See,* Note 6 – “Long-Term Debt – Loan Facility with Deerfield.”

For our development programs, while we currently intend to retain all rights and commercialize our approved products in the U.S., we are focused on identifying potential strategic alliances to assist us in markets outside the U.S. We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as, if our products are approved, an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our activities, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. In 2013, we are focused on securing a significant strategic alliance predominantly focused on the European Union (EU). To date, the primary focus of our discussions has been on AEROSURF. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in our SURFAXIN new drug application (NDA) approved by the FDA.

There can be no assurance that we will be successful in concluding any strategic alliance, collaboration or other similar transaction. See, Note 2 – Liquidity Risks and Management's Plans.

Note 2 – Liquidity Risks and Management's Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing and potential commercialization activities, and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, draw downs under a series of Committed Equity Financing Facilities (CEFFs) and a previous at-the-market program that we entered into in December 2011 with Lazard Capital Markets, capital equipment and debt facilities, and strategic alliances.

As of March 31, 2013, we had cash and cash equivalents of $26.4 million and approximately $7 million of accounts payable and accrued expenses and $10 million of long-term debt under the Deerfield Facility (discussed below). As a result of the delay in commercial availability of SURFAXIN drug product from the second quarter potentially to the fourth quarter of 2013, we have assessed and made adjustments to our strategic plan. Since we expect a moderate delay of up to six months, we intend to maintain our U.S. commercial and medical affairs capabilities and plan to continue investments in activities necessary to potentially advance our AEROSURF program and initiate a planned phase 2 clinical program in the fourth quarter of 2013. We also have adopted a plan intended to conserve cash resources by pacing certain other investments in our operations and commercial and development programs through the fourth quarter of 2013. To execute this business strategy and fund our operations, we will require significant additional infusions of capital until such time as the net revenues from SURFAXIN and AFECTAIR, from potential strategic alliance and collaboration arrangements and from other sources are sufficient to offset our cash flow requirements. Such infusions of capital could come from potential strategic alliances and collaboration arrangements, debt financings, public offerings and other similar transactions. Before additional financings, if any, including under our ATM Program (discussed below) and Deerfield Facility, we anticipate that we have sufficient cash available to support our operations and debt service obligations into the fourth quarter of 2013. Since a second $20 million payment under the Deerfield Facility will not be disbursed until we complete the first commercial sale of SURFAXIN drug product, our access to funds under the Deerfield Facility is also delayed, potentially until the fourth quarter of 2013. If we are unable to complete the first commercial sale of SURFAXIN drug product on or before December 31, 2013, our ability to access funds under the Deerfield Facility, will expire. Even if we succeed and both SURFAXIN drug product and AFECTAIR are introduced commercially as planned, given the time required to secure formulary acceptance of SURFAXIN at our target hospitals and acceptance of a new product, we expect our revenues from SURFAXIN and AFECTAIR to be modest in the first 12-18 months and then increase over time as our products gain hospital acceptance. Our investments in our operations, debt service and development programs are expected to outpace the rate at which we may generate revenues for several years.

The accompanying interim unaudited financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As a result of our cash position as of December 31, 2012, the audit opinion we received from our independent auditors for the year ended December 31, 2012 contains a notation related to our ability to continue as a going concern. Whether we can continue as a going concern is dependent upon our ability to raise additional capital, fund our research and development and commercial programs, and meet our obligations on a timely basis. If we are unable to secure sufficient additional capital, through strategic partnerships and collaborative arrangements, debt and/ or equity financings and other similar transactions, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit our development and commercial programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to secure the necessary capital, we may be forced to curtail all activities and, ultimately, cease operations. Even if we are able to raise additional capital, such transactions may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our March 31, 2013 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

To secure the necessary capital, we would prefer to enter into strategic alliances or collaboration agreements that 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) and, if approved, the introduction of our approved products in various markets outside the U.S. We also expect that we may secure $20 million additional capital under our Deerfield Facility, if we are able to complete the first commercial sale of SURFAXIN drug product on or before December 31, 2013. We also will consider equity public offerings. Through our ATM Program, we have the ability to sell up to $25 million of common stock at such times and in such amounts that we deem appropriate. Under our 2010 CEFF with Kingsbridge Capital Ltd. (Kingsbridge), we may sell to Kingsbridge up to approximately 1.1 million shares of our common stock, which based on the closing market price of our common stock on May 1, 2013 ($1.68), could result in proceeds to us of approximately $1.7 million. However, we may not meet the conditions to gain access to the funds available under the Deerfield Facility, the ATM Program can be cancelled at any time by either us or Stifel, and our 2010 CEFF will expire June 11, 2013. We also plan to consider other public and private equity offerings as well as financing transactions, such as secured equipment financing facilities or other similar transactions.

Our future capital requirements depend upon many factors, primarily the success of our efforts to (i) execute the commercial introduction of SURFAXIN and AFECTAIR in the U.S., as planned; (ii) advance the AEROSURF development program to initiation of the planned phase 2 clinical program in the fourth quarter of 2013; and (iii) secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, the commercial introduction of SURFAXIN, SURFAXIN LS, AFECTAIR and AEROSURF in markets outside the U.S. We believe that our ability to enter into a significant strategic alliance will likely improve if we remain on track to initiate both the commercial sale of SURFAXIN and our AEROSURF phase 2 clinical program in the fourth quarter of 2013. There can be no assurance, however, that our efforts will be successful, or that we will be able to obtain additional capital to support our activities when needed on acceptable terms, if at all.

As of March 31, 2013, 100 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 37.6 million shares of common stock were available for issuance and not otherwise reserved.

In February 2013, we entered into a loan facility (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield), pursuant to which Deerfield agreed to loan to us up to $30 million on a secured basis. Deerfield advanced $10 million upon execution of the agreement and agreed to advance an additional $20 million upon the first commercial sale of SURFAXIN drug product, provided that such sale occurs on or before December 31, 2013. In connection with the first disbursement, we issued to Deerfield a warrant to purchase approximately 2.3 million shares at an exercise price of $2.81. *See*, Note 6 – “Long-term Debt – Loan Facility with Deerfield.” Under the Deerfield Facility, interest accrues at a rate of 8.75% and is payable quarterly in cash. Principal is payable beginning on the fourth anniversary of the loan and is subject to further deferral as provided in the Deerfield Facility. For the quarter ended March 31, 2013, we accrued and paid interest in the amount of $0.1 million. Also in February 2013, we entered into an At-the-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated (Stifel), pursuant to which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell over a three-year period up to a maximum of $25 million of our common stock through an at-the-market program (ATM Program). We are not required to sell any shares at any time during the term of the ATM Program. We will pay Stifel a commission for each transaction equal to 3% of the gross proceeds. *See*, Note 4 – “Stockholders’ Equity – At-the-Market Program (ATM Program)”.

In addition, as of March 31, 2013, we had outstanding warrants to purchase approximately 10.3 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, approximately 4.9 million are February 2011 five-year warrants, which contain anti-dilution 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 warrants. These warrants were issued at an exercise price of $3.20 per share, which was adjusted downward to $2.80 per share following a public offering conducted at an offering price of $2.80 per share in March 2012. As of March 31, 2013, 4,948,750 of the February 2011 five-year warrants were outstanding. The holders of the Deerfield Warrants may exercise the warrants either for cash or on a cashless basis. In addition, in lieu of paying cash, the holders may elect to reduce the principal amount of the Deerfield loan to satisfy the exercise price of the warrants upon exercise. Although we believe that, in the future, we will secure additional capital from the exercise of at least a portion of our outstanding warrants, 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. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

Although we currently believe that we will be able to execute our revised strategic plan and accomplish our objectives, there can be no assurance that we will be successful. We require additional capital to satisfy our debt obligations, sustain operations, and complete the development and support the commercial introduction of our products, including SURFAXIN and AFECTAIR and, if approved, AEROSURF and potentially SURFAXIN LS. There can be no assurance that we will be successful in securing the needed capital, through strategic alliances, collaboration arrangements, financings, debt arrangements and other transactions. Failure to secure the necessary additional capital would have a material adverse effect on our business, financial condition and results of operations.

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 U.S. 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, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. There have been no changes to our critical accounting policies since December 31, 2012. 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, 2012 that we filed with the Securities and Exchange Commission (SEC) on March 15, 2013 (2012 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. We assess the potential capitalization of inventory and the timing of when the related costs are expected to be recoverable through the commercialization of our products. Costs incurred prior to FDA approval of SURFAXIN and the registration of our initial AFECTAIR device have been recorded in our statement of operations as research and development expense. Due to the delay in the commercial launch of SURFAXIN, previously capitalized raw material costs of $195,072 were charged to research & development expense in the first quarter of 2013, as these raw materials will no longer be used for commercial production.

Research and development expense

We track research and development expense by activity, as follows: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs. Research and development expense includes personnel, facilities, manufacturing and quality 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) upon FDA approval of SURFAXIN, in accordance with terms of our license agreement with J&J.

Net loss per common share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. For the quarters ended March 31, 2013 and 2012, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 15.8 million and 13.2 million shares, respectively. As a result of the Company's net losses for the periods presented, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

Recent accounting pronouncements
There were no new accounting pronouncements issued during the three months ended March 31, 2013 that are expected to have a material impact on the Company’s financial position, operating results or disclosures.

Note 4 – Stockholders’ Equity

At-the-Market Program (ATM Program)

On February 11, 2013, we entered into an At-the-Market Equity Offering Sales Agreement (ATM Program) with Stifel pursuant to which Stifel, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell up to a maximum of $25 million of our common stock over a three-year period. We are not required to sell any common stock at any time during the term of the ATM Program. If we issue a sale notice to Stifel, we may designate the minimum price per share at which our common stock may be sold and the maximum number of shares that Stifel is directed to sell during any selling period. As a result, prices are expected to vary as between purchasers and during the term of the offering. Stifel may sell shares by any method deemed to be an “at-the-market” equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, which may include ordinary brokers’ transactions on The Nasdaq Capital Market, or otherwise at market prices prevailing at the time of sale or prices related to such prevailing market prices, or as otherwise agreed by Stifel and us. The shares to be offered under the ATM Program are registered under our universal shelf registration statement on Form S-3 that we filed with the SEC on June 8, 2011 (2011 Universal Shelf).

Either party may suspend the ATM Program by notice to the other party. The ATM Program will terminate upon the earliest of: (1) the sale of all shares of common stock issuable thereunder, (2) February 11, 2016 or (3) other termination in accordance with the terms of the related agreement. Either party may terminate the ATM Program at any time upon written notification to the other party in accordance with the related agreement.

We have agreed to pay Stifel a commission equal to 3.0% of the gross sales price of shares sold pursuant to the ATM Program. With the exception of expenses related to the shares of common stock, Stifel will be responsible for all of its own costs and expenses incurred in connection with the ATM Program.

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, 2013 and December 31, 2012:

	Fair Value	Fair value measurement using		
	March 31, 2013	Level 1	Level 2	Level 3
Assets:				
Money Market	$ 22,877	$ 22,877	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 23,277	$ 23,277	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 6,143	$ –	$ –	$ 6,143

	Fair Value	Fair value measurement using		
	December 31, 2012	Level 1	Level 2	Level 3
Assets:				
Money Market	$ 23,377	$ 23,377	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 23,777	$ 23,777	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 6,305	$ –	$ –	$ 6,305

The table below summarizes the activity of Level 3 inputs measured on a recurring basis for the three months ended March 31, 2013 and 2012:

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2012	$ 6,305
Change in fair value of common stock warrant liability	(162)
Balance at March 31, 2013	$ 6,143

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

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

Significant Unobservable Input Assumptions of Level 3 Valuations	March 31, 2013	December 31, 2012
Historical Volatility	60%-79%	56% -80%
Expected Term (in years)	1.1 – 2.9	1.4 – 3.2
Risk-free interest rate	0.14% - 0.36%	0.16% - 0.36%

Fair Value of Long-Term Debt

As of March 31, 2013, the carrying value of the long-term debt, net of discounts, approximates fair value.

Note 6 – Long-term Debt

Loan Facility with Deerfield

On February 13, 2013, we entered into a secured loan facility with affiliates of Deerfield Management Company, L.P. (Deerfield) for up to $30 million in financing in 2013 (Deerfield Facility). Deerfield advanced to us $10 million upon execution of the agreement and agreed to advance an additional $20 million, subject to certain conditions, on or about the date of the first commercial sale of SURFAXIN drug product (Milestone Date), provided that the first commercial sale occurs on or before December 31, 2013. The loan may be prepaid in whole or in part without penalty at any time. In addition, the principal amount of the loan may be reduced to the extent that a holder of the notes elects to apply a portion of the principal amount outstanding to satisfy the exercise price of related Warrants (see below) upon exercise of all or a portion of the Warrants.

The principal amount of the loan is payable in equal annual installments on the fourth, fifth and sixth anniversaries of the facility agreement, provided that the amount payable on the fourth anniversary shall be deferred for one year if either (i) our "Net Sales" (defined below) for the immediately preceding 12-month period are at least $20 million, or (ii) our "Equity Value" (defined below) is at least $200 million; and provided further, that the amount payable on the fifth anniversary (together with any amount deferred on the fourth anniversary) shall be deferred until the sixth anniversary if either (x) our "Net Sales" for the immediately preceding 12 month period are at least $30 million, or (ii) our "Equity Value" is at least $250 million. For the purposes of the foregoing deferrals of principal, "Net Sales" means, without duplication, the gross amount invoiced by us or on our behalf, any of our subsidiaries or any direct or indirect assignee or licensee for products, sold globally in bona fide, arm's length transactions, less customary deductions determined without duplication in accordance with generally accepted accounting principles; and "Equity Value" means, with respect to each measurement date, the product of (x) the number of issued and outstanding shares of our common stock on such measurement date multiplied by (y) the per share closing price of our common stock on such measurement date. Accordingly, if the milestones are achieved in each year, payment of the principal amount could be deferred until the sixth anniversary date of the loan on February 13, 2019.

Any amounts received under the Deerfield Facility will accrue interest at a rate of 8.75%, payable quarterly in cash. The facility agreement contains customary terms and conditions but does not require us to meet minimum financial and revenue performance covenants. In connection with each advance, Deerfield has received and may receive a transaction fee equal to 1.5% of any amount disbursed. The facility agreement also contains various representations and warranties and affirmative and negative covenants customary for financings of this type, including restrictions on our ability to incur additional indebtedness and grant additional liens on its assets. In addition, all amounts outstanding under the Deerfield Facility may become immediately due and payable upon (i) an "Event of Default," as defined in the facility agreement, in which case Deerfield would have the right to require us to repay the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the occurrence of certain events as defined in the facility agreement, including, among other things, the consummation of a change of control transaction or the sale of more than 50% of the Company's assets (a Major Transaction).

In connection with the execution of the Deerfield Facility and receipt of the initial disbursement of $10 million, we issued to Deerfield warrants to purchase an aggregate of 2,340,000 shares of our common stock at an exercise price of $2.81 per share of common stock, representing a 24% premium to the closing price of our common stock on the Nasdaq Capital Market on the immediately preceding trading day. If the Milestone Date, as defined in the facility agreement, occurs, upon disbursement of the additional $20 million loan under the facility agreement, we will issue warrants to purchase an additional 4,660,000 shares of our common stock at an exercise price of $2.81 per share of common stock (together with the warrants in the preceding sentence, the "Warrants"). There can be no assurance that the Milestone Date will occur. The number of shares of common stock into which a Warrant is exercisable and the exercise price of any Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock.

Each Warrant issued under the Deerfield Facility will expire on the sixth anniversary of the facility agreement and contains certain limitations that generally prevent the holder from acquiring shares upon exercise of a Warrant that would result in the number of shares beneficially owned by it to exceed 9.985% of the total number of shares of common stock then issued and outstanding. The holder of a Warrant may exercise all or a portion of the Warrant either for cash or on a cashless basis. In connection with a Major Transaction, as defined in the Warrants, to the extent of consideration payable to stockholders in cash in connection with such Major Transaction, the holder may have the option to redeem the Warrant or that portion of the Warrant for cash in an amount equal to the Black-Scholes value (as defined in the Warrant) of the Warrant or that portion of the Warrant redeemed. In addition, in connection with a Major Transaction, to the extent of any consideration payable to stockholders in securities, or in the event of an Event of Default, the holder may have the option to exercise the Warrant and receive therefor that number of shares of Common Stock that equals the Black-Scholes value of the Warrant or that portion of the Warrant exercised. Prior to the holder exercising the Warrant for shares in such transactions, the Company may elect to terminate the Warrant or that portion of the Warrant and pay the holder cash in an amount equal to the Black-Scholes value of the Warrant.

We have recorded the loan as long-term debt at its face value of $10.0 million less debt discounts and issuance costs consisting of (i) $3.8 million fair value of the 2,340,000 Warrants issued upon the advance of the $10 million initial disbursement; and (ii) a $150,000 transaction fee. The discount is being accreted to the $10 million loan over its term using the effective interest method. The Warrants are derivatives that qualify for an exemption from liability accounting as provided for in Accounting Standards Codification (ASC) Topic 815 *"Derivatives and Hedging – Contracts in Entity's Own Equity"* (ASC 815) and have been classified as equity.

The fair value of the 2,340,000 Warrants was calculated using the Black-Scholes option-pricing model. The significant Level 3 unobservable inputs used in valuing the Warrants are the historical volatility of our common stock market price, expected term of the warrants, and the risk-free interest rate based on the U.S. Treasury yield curve in effect at the measurement date. Any significant increases or decreases in the unobservable inputs, with the exception of the risk-free interest rate, would have resulted in a significantly higher or lower fair value measurement.

Significant Unobservable Input Assumptions of Level 3 Valuations	
Historical Volatility	101%
Expected Term (in years)	6.0
Risk-free interest rate	0.12%

Long-term debt as of March 31, 2013 consists solely of amounts due under the Deerfield Facility as follows:

Note Payable	$	10,000
Unamortized discount		(3,917)
Long-term debt, net of discount	$	$ 6,083

The following amounts comprise interest expense under the Deerfield Facility for the three months ended March 31, 2013:

Cash interest expense	$	113
Non-cash amortization of debt discount		57
Amortization of debt costs		5
Total interest expense	$	175

Cash interest expense represents interest of 8.75% on the principal amount outstanding under the Deerfield Facility for the period that is to be paid in cash. Non-cash amortization of debt discount represents the amortization of the fair value of the warrants issued in connection with the Deerfield Facility. The amortization of debt costs represents the transaction fee and legal costs incurred in connection with the Deerfield Facility.

Note 7 – Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815, either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

The registered warrants that we issued in May 2009 and February 2010 have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using the Black-Scholes option-pricing model. The February 2011 five-year warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model. (*See*, Note 8 in our 2012 Form 10-K for a discussion of the common stock warrant liability.)

Selected terms and estimated fair value of warrants accounted for as derivative liabilities at March 31, 2013 are as follows:

Issuance Date	Number of Warrant Shares		Exercise Price	Warrant Expiration Date	Fair Value of Warrants (in thousands) Issuance Date		March 31, 2013
5/13/2009	466,667	$	17.25	5/13/2014	$ 3,360	$	–
2/23/2010	916,669		12.75	2/23/2015	5,701		33
2/22/2011	4,948,750		2.80	2/22/2016	8,004		6,110

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 8 – 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 for employees is typically three years.

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,	
	2013	2012
Weighted-average expected volatility	110%	113%
Weighted-average expected term	4.8 years	4.8 years
Weighted-average risk-free interest rate	0.74%	0.79%
Expected dividends	–	–

The total stock-based employee compensation for the three months ended March 31, 2013 and 2012 was as follows:

(in thousands)	Three Months Ended March 31,	
	2013	2012
Research & Development	$ 141	$ 120
Selling, General & Administrative	215	278
Total	$ 356	$ 398

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

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks and uncertainties. You should review the "Forward-Looking Statements" section, and the risk factors discussed in the "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, as well as in our Annual Report on Form 10-K for the year ended December 31, 2012 that we filed with the Securities and Exchange Commission (SEC) on March 15, 2013 (2012 Form 10-K) and our other filings with the Securities and Exchange Commission (SEC), and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.

Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is provided as a supplement to the accompanying interim unaudited consolidated financial statements and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. This item should be read in connection with our accompanying interim unaudited consolidated financial statements (including the notes thereto).

OVERVIEW

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on creating life-saving products for critical care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug technology produces a synthetic, peptide-containing surfactant (KL4 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 KL4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of aerosolized drugs, including our aerosolized KL4 surfactant, and other inhaled therapies. We believe that our proprietary technologies make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

Our initial strategy is to develop our KL4 surfactant and drug delivery technologies to improve the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants, and the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs have the potential to greatly improve the management of RDS and, collectively over time, to become a new standard of care for premature infants with RDS.

In March 2012, the United States (U.S.) Food and Drug Administration (FDA) granted us marketing approval for SURFAXIN® (lucinactant) for the prevention of 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. In the third quarter of 2012, during a routine review of our processes related to analytical testing and quality control of SURFAXIN drug product, we determined that one analytical chemistry method used to assess SURFAXIN drug product required improvement and that an update to SURFAXIN product specifications was needed. We promptly communicated with the FDA, improved and revalidated the analytical chemistry method, and submitted updated product specifications to the FDA. As a result, we estimated that the commercial availability of SURFAXIN drug product would be delayed until the second quarter 2013. We did not believe that the delay would have a material impact on our plans. However, in April 2013, the FDA requested information and provided recommendations intended to clarify certain aspects of the updated product specifications and our revalidated analytical chemistry method, including recommendations regarding how the product specifications should be documented and notated; a specific recommendation for the upper limit of a single product specification, which we can readily accept; a request for two existing documents related to the improved analytical chemistry method; and a request for supporting data from the improved and revalidated analytical chemistry method used on recent SURFAXIN batches. We believe that we will be able to respond to the FDA by early June. Based on the FDA's guidelines, which provide for four months for a review of our type of submission, we anticipate that, if we are successful and our submission is timely confirmed by the FDA, we will be able to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013. There can be no assurance, however, that the FDA will respond within the time line set forth in its guidelines or accept our proposed updated product specifications. Any extended delay in the commercial availability of SURFAXIN could have a material adverse effect on our ability to fund our operations and our development programs.

AEROSURF® is a drug/device combination product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG). 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 frequently result in serious respiratory conditions and complications. Consequently, neonatologists generally will not treat infants who could benefit from surfactant therapy unless they determine that 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.

We are developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that is stored as a powder and resuspended to liquid form prior to use with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are engaged in a technology transfer of our lyophilized KL4 surfactant manufacturing process to a contract manufacturing organization (CMO) that has expertise in lyophilized products, and we expect that it will manufacture drug product for use in our preclinical and clinical development activities. This development plan is intended initially to support the use of our lyophilized KL4 surfactant in our AEROSURF development program. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially in other major markets.

AFECTAIR® devices are our novel disposable aerosol-conducting airway connectors that simplify the delivery of aerosolized medications (including our aerosolized KL4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. In February 2012, we registered our AFECTAIR device in the U.S. as a Class I, exempt medical device. Our initial device is AFECTAIR aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal or pediatric intensive care units (NICUs and PICUs, respectively). We are conducting a user experience program in select U.S. critical care centers representing approximately ten percent (10%) of our target institutions. This program is intended to facilitate peer-to-peer exchange among physicians and respiratory therapists and enable discussion about the potential advantages and proper utilization of this novel device, and is expected to be conducted through the first half of 2013. We believe that AFECTAIR aerosol-conducting airway connectors have the potential to become a new standard of care for the delivery of aerosolized medications and inhaled therapies to infants receiving aerosolized medication in the NICU and PICU. We believe that revenues from the AFECTAIR device for infants in the fourth full selling year could potentially be $10 million in the U.S. and $20 million globally.

We expect that we will be able to leverage the information, data and know-how that we gain from our development efforts with AEROSURF for RDS and the AFECTAIR device for infants to support development of a product pipeline intended to address serious critical care respiratory conditions of larger children and adults in PICUs and intensive care units (ICUs). However, we are delaying these efforts as we focus our resources on advancing the development of AEROSURF to phase 2 clinical trials and the commercial introduction of SURFAXIN and the AFECTAIR device for infants. If we are able to achieve these 2013 objectives, we believe we will be in a better position to assess the potential of developing products based on our CAG and aerosol-conductor airway connector technologies to address the critical care needs of patients in the PICU and ICU.

In the U.S., we have established our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in neonatal/pediatric respiratory critical care, and will focus on neonatal indications beginning with SURFAXIN and the AFECTAIR device for infants. These organizations will be primarily responsible to effect the commercial introduction of SURFAXIN. With our established relationships and contacts in the neonatal community, we believe that we also will be able to use our commercial and medical affairs organizations to effectively introduce the AFECTAIR device for infants in the U.S. We also expect that, in the future, these teams will be able to leverage the experience and relationships that we gain with the introduction of SURFAXIN and the AFECTAIR device for infants to efficiently support the introductions of AEROSURF and potentially SURFAXIN LS, if approved.

An important priority for us is to secure strategic and financial resources to support our operations and to advance our KL_4 surfactant and device development programs and the commercial introduction of our RDS products. We currently expect that the delay in commercial availability of SURFAXIN will most likely be for a period of up to six months and, accordingly, have decided to maintain our investments in commercial and medical affairs capabilities and development activities necessary to advance our AEROSURF development program potentially to initiate the planned phase 2 clinical program in the fourth quarter of 2013. We otherwise plan to slow the pace of our investments and manage our cash resources while we seek to secure the necessary capital from various potential sources, including debt and equity financings, strategic partnerships and collaboration arrangements and other transactions. The recent delay in the commercial availability of SURFAXIN has delayed access to a $20 million advance, which is payable upon the first commercial sale of SURFAXIN, under a loan facility (Deerfield Facility) with affiliates of Deerfield Management Compnay, L.P. (Deerfield). If for any reason, we are unable to complete the first commercial sale of SURFAXIN by December 31, 2013, our ability to access the $20 million under the Deerfield Facility will expire. *See*, "– Liquidity and Capital Resources – Loan Facility with Deerfield."

For our development programs, while we currently intend to retain all rights and commercialize our approved products in the U.S., we are focused on identifying potential strategic alliances to assist us in markets outside the U.S. We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as, if our products are approved, an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our activities, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. In 2013, we are focused on securing a significant strategic alliance predominantly focused on the European Union (EU). To date, the primary focus of our discussions has been on AEROSURF. We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in our SURFAXIN new drug application (NDA) approved by the FDA.

There can be no assurance that we will be successful in securing the necessary capital, or concluding any strategic alliance, collaboration or other similar transaction. *See*, "– Liquidity and Capital Resources."

Business and Pipeline Programs Update

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business," in our 2012 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.

Following are updates to our pipeline programs since the filing of our 2012 Form 10-K:

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

  In April 2013, we received a response from the FDA to the submission that we made in the fourth quarter of 2012. The FDA requested clarification and provided recommendations regarding our recently updated product specifications for SURFAXIN drug product. The FDA correspondence included a request for specific information intended to clarify certain aspects of the updated product specifications and the revalidated analytical chemistry method, including recommendations regarding how the product specifications should be documented and notated; a specific recommendation for the upper limit of a single product specification, which the Company can readily accept; a request for two existing and readily available documents related to the improved analytical chemistry method; and a request for supporting data using the recently improved and revalidated analytical chemistry method that is being generated from recent SURFAXIN batches. We plan to provide a response to the FDA early June. FDA guidelines provide up to four months for it to review our type of submission. Based on the anticipated time required to respond and await confirmation from the FDA, we anticipate that, if our plan is successful and confirmed by the FDA within this timeline, we expect to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013.

- AFECTAIR

  With respect to our AFECTAIR aerosol-conducting airway connectors for infants, we are conducting a user experience program in select U.S. critical care centers that is intended to facilitate peer-to-peer exchange among physicians and respiratory therapists and enable discussion about the potential advantages and proper utilization of this novel device, and is expected to be conducted through the first half of 2013.

- AEROSURF and SURFAXIN LS Development Programs

  We continue our efforts to optimize the design of our CAG and are working with Battelle Memorial Institute (Battelle) to complete the development and manufacture clinic-ready CAG devices for our planned AEROSURF phase 2 clinical trials. We remain on track to initiate the initial phase of our phase 2 clinical program in the fourth quarter of 2013.

  We continue to work on a technology transfer of our lyophilized KL4 surfactant manufacturing process to a contract manufacturing organization (CMO) that has expertise in lyophilized products, and we expect that it will manufacture drug product for use in our AEROSURF clinical program in the fourth quarter of 2013. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially in other major markets

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2012. 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 2012 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the three months ended March 31, 2013 and 2012 was $12.6 million (or $0.29 per share) and $10.0 million (or $0.37 per share), respectively. Included in the net loss for the three months ended March 31, 2013 and 2012 was the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.2 million and non-cash expense of $3.4 million, respectively.

The operating loss for the three months ended March 31, 2013 and 2012 was $12.6 million and $6.6 million, respectively. The increase in operating loss from 2012 to 2013 is primarily due to (i) a $2.7 million investment to establish our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in neonatal/pediatric respiratory critical care and will focus on neonatal indications, beginning with SURFAXIN and the AFECTAIR device for infants, (ii) a $1.6 million increase in investment to advance the AEROSURF development program, primarily the optimization of our CAG and the technology transfer of our lyophilized KL4 surfactant manufacturing process to a CMO, and (iii) a $1.3 million increase in purchases of raw materials for drug product manufacturing in support of the potential commercial availability of SURFAXIN and our AEROSURF development program.

Grant Revenue

For the three months ended March 31, 2013, we recognized $0.1 million of grant revenue for funds received and expended under a Small Business Innovation Research (SBIR) Phase I award from National Institute of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) Center for Medical Counter Measures Against Radiation and Nuclear Threats to assess the ability of KL4 surfactant to mitigate the effects of acute radiation exposure to the lung, including acute pneumonitis and delayed lung injury. We believe that our aerosolized KL4 surfactant may be an effective intervention for people at risk for, or with, Acute Lung Injury (ALI), and that our development work with AEROSURF for RDS may form the basis for a pipeline of products to address ALI. We are collaborating with leading research institutions in a series of preclinical studies funded through various U.S. government-sponsored, biodefense-related initiatives, including NIAID. The total amount of the award is $0.6 million and funds received and expended from inception of the award through March 31, 2013 have totaled $0.3 million. The remainder of the award is expected to be received and expended in 2013. We did not recognize any grant revenues for the comparable period in 2012.

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 of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist primarily of expenses associated with (a) 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, 2013 and 2012 are as follows:

(in thousands) Research and Development Expenses	Three Months Ended March 31, 2013	2012
Product development and manufacturing	$ 6,824	$ 3,103
Medical and regulatory operations	1,451	823
Direct preclinical and clinical programs	197	607
Total Research & Development Expenses	$ 8,472	$ 4,533

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.3 million and $0.4 million for the three months ended March 31, 2013 and 2012, respectively.

As a result of the recent delay in commercial availability of SURFAXIN drug product from the second quarter of 2013 until potentially the fourth quarter of 2013, we have reviewed our expenses with a view to slowing the pace of certain investments and conserving cash resources until we are able to secure the additional capital required to support our operations and development programs. However, we plan to continue selective investments in our medical affairs capabilities to provide scientific and medical education support related to both SURFAXIN and AFECTAIR and certain key initiates, including development activities to advance the AEROSURF program potentially to a planned phase 2 clinical program in the fourth quarter of 2013.

Product Development and Manufacturing

Product development and manufacturing includes (i) the cost of our manufacturing operations and technical transfer of our lyophilized manufacturing process to a CMO, validation activities and 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 primarily for use in our anticipated AEROSURF clinical program; (iii) design and development activities related to our AFECTAIR aerosol-conducting airway connectors, and; (iv) pharmaceutical development activities, including development of a lyophilized dosage form of our KL4 surfactant. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities, analytical services, and expert consultants and outside services to support pharmaceutical and device development activities.

Product development and manufacturing expenses increased $3.7 million from 2012 to 2013 primarily due to (i) investments in our manufacturing and quality activities as we prepare for commercial introduction of SURFAXIN and the AFECTAIR device for infants; (ii) costs associated with our efforts to optimize the design of our CAG with our engineering staff and third-party medical device experts, including work that we began in June 2012 with Battelle Memorial Institute (Battelle), which is assisting to optimize design, test, and manufacture clinic-ready CAG devices to be used in our AEROSURF phase 2 clinical trials, which we expect to initiate in the fourth quarter of 2013; (iii) costs associated with the technical transfer of our lyophilized manufacturing process to a CMO; and, (iv) purchases of active pharmaceutical ingredients (APIs) used in the production of SURFAXIN for development and commercial purposes as well as to support the technical transfer of our lyophilized manufacturing process to a CMO, and development of our CAG for use in our anticipated AEROSURF clinical program.

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 related to both SURFAXIN and AFECTAIR as well as our other KL4 surfactant and aerosol delivery products under development. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Medical and regulatory operations costs increased $0.6 million from 2012 to 2013 primarily due to investment in our medical affairs organization to support the commercial introduction of SURFAXIN and the AFECTAIR device for infants.

To support the commercial introduction of SURFAXIN and AFECTAIR, we expect to incur expenses at an initial annual rate of approximately $13 million. Of this amount, the portion attributed to medical affairs, anticipated to be approximately $3 million, will be charged to medical and regulatory operations expenses. *See also*, "– Selling, General and Administrative Expenses."

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) development activities, including preparatory activities for the anticipated clinical program for AEROSURF for RDS in premature infants and, potentially, SURFAXIN LS, toxicology studies and other preclinical studies to obtain data to support potential Investigational New Drug (IND) and New Drug Application (NDA) filings for our product candidates; and (ii) activities, if any, associated with conducting clinical trials, including patient enrollment costs, external site costs, clinical drug supply and related external costs, such as research consultant fees and expenses.

Direct preclinical and clinical programs expense decreased $0.4 million from 2012 to 2013 primarily due to a $0.5 million charge in 2012 related to a milestone payment that became payable to Johnson and Johnson (J&J) upon FDA approval of SURFAXIN in March 2012.

We plan to continue to focus our drug research and development activities on the management of RDS in premature infants, specifically AEROSURF, and our lyophilized KL4 surfactant development programs, which we expect to use for AEROSURF. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially other major markets. To prepare for initiation of our AEROSURF clinical program, we previously conducted preliminary meetings with the FDA and we have engaged regulatory consultants to assist us in implementing and, as needed, refining our development plan. We also plan to retain regulatory consultants to assist us in engaging with international regulatory authorities regarding the AEROSURF development plan. We expect that we will use our lyophilized KL4 surfactant for AEROSURF. We also previously discussed with the FDA a proposed development program for SURFAXIN LS and expect to engage in further discussions with the FDA in this regard. We plan to initiate the first phase of the AEROSURF phase 2 clinical program in the fourth quarter of 2013. As resources permit, we plan to leverage the development investments to date in our aerosol technology programs (AEROSURF and AFECTAIR) to address respiratory critical care conditions in larger children and adults, including potentially ALI.

Research and Development Projects – Updates

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete individual projects in development are not reasonably estimable. With every phase of a development project, there are unknowns that may significantly affect cost projections and timelines. As a result of the number and nature of these factors, many of which are outside our control, the success, timing of completion and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. Certain of the risks and uncertainties affecting our ability to estimate projections and timelines are discussed in the Risk Factors Section and elsewhere in this Quarterly Report on Form 10-Q and in our 2012 Form 10-K, including in "Item 1 – Business – Government Regulation;" "Item 1A – Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Research and Development Expenses."

Our lead development projects are initially focused on (i) the management of RDS in premature infants and include SURFAXIN, AEROSURF and SURFAXIN LS; and (ii) development of our aerosol delivery technologies, including our CAG and proprietary AFECTAIR aerosol-conducting airway connectors. These and our other product programs are described in "– Overview – Business and Pipeline Programs Update," and in our other periodic filings with the SEC, including our 2012 Form 10-K, "Item 1 – Business – Proprietary Platform – Surfactant and Aerosol Technologies," and "- Surfactant Replacement Therapy for Respiratory Medicine."

The reader is referred to and encouraged to review updates to the Pipeline Programs Update in "– Overview," and "–Business and Pipeline Programs Update" in this MD&A, which contain information important to this discussion. As noted above, we have reviewed our development programs and plan to continue to advance our AEROSURF development program potentially to the planned phase 2 clinical program in the fourth quarter of 2013 and otherwise pace and limit our investments in other development activities until such time as we have secured required additional capital. *See*, "– Overview," and " Liquidity and Capital Resources."

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended March 31, 2013	2012
Selling, General and Administrative Expenses	$ 4,220	$ 2,047

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

Selling, general and administrative expenses increased $2.2 million from 2012 to 2013 due primarily to (i) investments in our marketing and field-based sales organization in preparation for the commercial introduction of SURFAXIN and the AFECTAIR device for infants; and (ii) marketing related costs for both SURFAXIN and the AFECTAIR device for infants.

To support the commercial introduction of SURFAXIN and AFECTAIR, we expect to incur expenses at an initial annual rate of approximately $13 million. Of this amount, the portion attributed to marketing and field-based sales, anticipated to be approximately $10 million, will be charged to selling, general and administrative expenses. *See also*, "– Medical and Regulatory Operations."

In addition to developing our commercial marketing and sales organization, we have made additional investments to enhance certain of our general and administrative resources, including legal and compliance, finance and accounting, and information technologies, to support the commercial introduction of SURFAXIN and the AFECTAIR device for infants.

As a result of the recent delay in commercial availability of SURFAXIN drug product from the second quarter of 2013 until potentially the fourth quarter of 2013, we have reviewed our expenses with a view to slowing the pace of certain investments and conserving cash resources until we are able to secure the additional capital required to support our operations and development programs. However, we plan to continue investments in certain key initiates, including in our marketing and field-based sales organization in preparation for the commercial introduction of SURFAXIN and the AFECTAIR device for infants. *See*, "– Overview," and " Liquidity and Capital Resources."

Other Income and (Expense)

Other income and (expense) for the three months ended March 31, 2013 and 2012 are as follows:

(Dollars in thousands)	Three months ended March 31, 2013	2012
Interest income	$ 1	$ 2
Interest expense	(178)	(4)
Other income / (expense), net	$ (177)	$ (2)

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 U.S. treasury-based money market fund.

Interest expense for 2013 consists of Deerfield Facility interest of $175,000 and $3,000 of interest incurred under our equipment financing facilities. Interest expense for 2012 consists of interest accrued under our equipment financing facilities.

The following amounts comprise the Deerfield Facility interest expense in 2013:

Cash interest expense	$ 113
Non-cash amortization of debt discount	57
Amortization of debt costs	5
Total interest expense	$ 175

Cash interest expense represents interest of 8.75% on the principal amount outstanding under the Deerfield Facility for the period that is to be paid in cash. Non-cash amortization of debt discount represents the amortization of the Black-Scholes pricing model fair value of the warrants issued in connection with the Deerfield Facility. The amortization of debt costs represents the transaction fee and legal costs incurred in connection with the Deerfield Facility.

Change in Fair Value of Common Stock Warrant Liability

(in thousands)	Three Months Ended March 31, 2013	2012
Change in fair value of common stock warrant liability (Income / (Expense))	$ 162	$ (3,434)

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"* (ASC 815), as either derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Derivative warrant liabilities are valued at the date of initial issuance and as of each subsequent balance sheet date using the Black-Scholes or trinomial pricing models, depending on the terms of the applicable warrant agreement. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability." *See*, Notes 6 and 7 to our Consolidated Financial Statements in this Quarterly Report on Form 10-Q, and, in our 2012 Form 10-K, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Change in Fair Value of Common Stock Warrant Liability."

Changes in the fair value of common stock warrant liability are due primarily to changes in our common stock share price during the periods.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have incurred substantial losses since inception, due to investments in research and development, manufacturing and potential commercialization activities, and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, draw downs under a series of Committed Equity Financing Facilities (CEFFs) and a previous at-the-market program that we entered into in December 2011 with Lazard Capital Markets, capital equipment and debt facilities, and strategic alliances.

As of March 31, 2013, we had cash and cash equivalents of $26.4 million and approximately $7 million of accounts payable and accrued expenses and $10 million of long-term debt under the Deerfield Facility (discussed below). As a result of the delay in commercial availability of SURFAXIN drug product from the second quarter potentially to the fourth quarter of 2013, we have assessed and made adjustments to our strategic plan. Since we expect a moderate delay of up to six months, we intend to maintain our U.S. commercial and medical affairs capabilities and plan to continue investments in activities necessary to potentially advance our AEROSURF program and initiate a planned phase 2 clinical program in the fourth quarter of 2013. We also have adopted a plan intended to conserve cash resources by pacing certain other investments in our operations and commercial and development programs through the fourth quarter of 2013. To execute this business strategy and fund our operations, we will require significant additional infusions of capital until such time as the net revenues from SURFAXIN and AFECTAIR, from potential strategic alliance and collaboration arrangements and from other sources are sufficient to offset our cash flow requirements. Such infusions of capital could come from potential strategic alliances and collaboration arrangements, debt financings, public offerings and other similar transactions. Before additional financings, if any, including under our ATM Program (discussed below) and Deerfield Facility (discussed below), we anticipate that we have sufficient cash available to support our operations and debt service obligations into the fourth quarter of 2013. Since a second $20 million payment under the Deerfield Facility will not be disbursed until we complete the first commercial sale of SURFAXIN drug product, our access to funds under the Deerfield Facility is also delayed, potentially until the fourth quarter of 2013. If we are unable to complete the first commercial sale of SURFAXIN drug product on or before December 31, 2013, our ability to access funds under the Deerfield Facility, will expire. Even if we succeed and both SURFAXIN drug product and AFECTAIR are introduced commercially as planned, given the time required to secure formulary acceptance of SURFAXIN at our target hospitals and acceptance of a new product, we expect our revenues from SURFAXIN and AFECTAIR to be modest in the first 12-18 months and then increase over time as our products gain hospital acceptance. Our investments in our operations, debt service and development programs are expected to outpace the rate at which we may generate revenues for several years.

The accompanying interim unaudited financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As a result of our cash position as of December 31, 2012, the audit opinion we received from our independent auditors for the year ended December 31, 2012 contains a notation related to our ability to continue as a going concern. Whether we can continue as a going concern is dependent upon our ability to raise additional capital, fund our research and development and commercial programs, and meet our obligations on a timely basis. If we are unable to secure sufficient additional capital, through strategic partnerships and collaborative arrangements, debt and/ or equity financings and other similar transactions, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit our development and commercial programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to secure the necessary capital, we may be forced to curtail all activities and, ultimately, cease operations. Even if we are able to raise additional capital, such transactions may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our March 31, 2013 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

To secure the necessary capital, we would prefer to enter into strategic alliances or collaboration agreements that 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) and, if approved, the introduction of our approved products in various markets outside the U.S. We also expect that we may secure $20 million additional capital under our Deerfield Facility, if we are able to complete the first commercial sale of SURFAXIN drug product on or before December 31, 2013. We also will consider equity public offerings. Through our ATM Program, we have the ability to sell up to $25 million of common stock at such times and in such amounts that we deem appropriate. Under our 2010 CEFF with Kingsbridge Capital Ltd. (Kingsbridge), we may sell to Kingsbridge up to approximately 1.1 million shares of our common stock, which based on the closing market price of our common stock on May 1, 2013 ($1.68), could result in proceeds to us of approximately $1.7 million. However, we may not meet the conditions to gain access to the funds available under the Deerfield Facility, the ATM Program can be cancelled at any time by either us or Stifel, and our 2010 CEFF will expire June 11, 2013. We also plan to consider other public and private equity offerings as well as financing transactions, such as secured equipment financing facilities or other similar transactions.

Our future capital requirements depend upon many factors, primarily the success of our efforts to (i) execute the commercial introduction of SURFAXIN and AFECTAIR in the U.S., as planned; (ii) advance the AEROSURF development program to initiation of the planned phase 2 clinical program in the fourth quarter of 2013; and (iii) secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, the commercial introduction of SURFAXIN, SURFAXIN LS, AFECTAIR and AEROSURF in markets outside the U.S. We believe that our ability to enter into a significant strategic alliance will likely improve if we remain on track to initiate both the commercial sale of SURFAXIN and our AEROSURF phase 2 clinical program in the fourth quarter of 2013. There can be no assurance, however, that our efforts will be successful, or that we will be able to obtain additional capital to support our activities when needed on acceptable terms, if at all.

As of March 31, 2013, 100 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 37.6 million shares of common stock were available for issuance and not otherwise reserved.

In February 2013, we entered into a loan facility (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield), pursuant to which Deerfield agreed to loan to us up to $30 million on a secured basis. Deerfield advanced $10 million upon execution of the agreement and agreed to advance an additional $20 million upon the first commercial sale of SURFAXIN drug product, provided that such sale occurs on or before December 31, 2013. In connection with the first disbursement, we issued to Deerfield a warrant to purchase approximately 2.3 million shares at an exercise price of $2.81. *See*, Note 6 – “Long-term Debt – Loan Facility with Deerfield.” Under the Deerfield Facility, interest accrues at a rate of 8.75% and is payable quarterly in cash. Principal is payable beginning on the fourth anniversary of the loan and is subject to further deferral as provided in the Deerfield Facility. For the quarter ended March 31, 2013, we accrued and paid interest in the amount of $0.1 million. Also in February 2013, we entered into an At-the-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated (Stifel), pursuant to which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell over a three-year period up to a maximum of $25 million of our common stock through an at-the-market program (ATM Program). We are not required to sell any shares at any time during the term of the ATM Program. We will pay Stifel a commission for each transaction equal to 3% of the gross proceeds. *See*, Note 4 – “Stockholders’ Equity – At-the-Market Program (ATM Program)”.

In addition, as of March 31, 2013, we had outstanding warrants to purchase approximately 10.3 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, approximately 4.9 million are February 2011 five-year warrants, which contain anti-dilution 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 warrants. These warrants were issued at an exercise price of $3.20 per share, which was adjusted downward to $2.80 per share following a public offering conducted at an offering price of $2.80 per share in March 2012. As of March 31, 2013, 4,948,750 of the February 2011 five-year warrants were outstanding. The holders of the Deerfield Warrants may exercise the warrants either for cash or on a cashless basis. In addition, in lieu of paying cash, the holders may elect to reduce the principal amount of the Deerfield loan to satisfy the exercise price of the warrants upon exercise. Although we believe that, in the future, we will secure additional capital from the exercise of at least a portion of our outstanding warrants, 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. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

Although we currently believe that we will be able to execute our revised strategic plan and accomplish our objectives, there can be no assurance that we will be successful. We require additional capital to satisfy our debt obligations, sustain operations, and complete the development and support the commercial introduction of our products, including SURFAXIN and AFECTAIR and, if approved, AEROSURF and potentially SURFAXIN LS. There can be no assurance that we will be successful in securing the needed capital, through strategic alliances, collaboration arrangements, financings, debt arrangements and other transactions. Failure to secure the necessary additional capital would have a material adverse effect on our business, financial condition and results of operations.

Cash Flows

As of March 31, 2013, we had cash and cash equivalents of $26.4 million compared to $26.9 million as of December 31, 2012. Cash outflows before financings for the three months ended March 31, 2013 consisted of $10.2 million used for ongoing operating activities and $0.1 million for purchases of property and equipment. The cash outflows before financings were offset by $10 million ($9.9 million net of expenses) advanced under the Deerfield Facility.

Operating Activities

Net cash used in operating activities was $10.2 million and $5.5 million for the three months ended March 31, 2013 and 2012, respectively.

Net cash used in operating activities is the result of our net loss for the period adjusted for non-cash items associated with the change in fair value of common stock warrants (income of $0.2 million in 2013 and expense of $3.4 million in 2012), stock-based compensation and depreciation and amortization expenses ($0.6 million in 2013 and $0.8 million in 2012); and changes in working capital.

The increase in net cash used in operating activities from 2012 to 2013 is primarily due to (i) investments in marketing, field-based sales and medical affairs capabilities, and manufacturing and quality activities in preparation for the commercial introduction of SURFAXIN and the AFECTAIR device for infants; (ii) costs associated with our efforts to optimize the design of our CAG with our engineering staff and third-party medical device experts, including work that we began in June 2012 with Battelle to optimize design, test, and manufacture clinic-ready CAG devices to be used in the first phase of our planned AEROSURF phase 2 clinical trial, which we expect to initiate in the fourth quarter of 2013; and (iii) purchases of active pharmaceutical ingredients (raw materials) used in the production of SURFAXIN for commercial purposes as well as to support the technical transfer of our lyophilized manufacturing process to a CMO, and development of our CAG for use in our anticipated AEROSURF clinical program.

Investing Activities

Net cash used in investing activities represents capital expenditures of $120,000 and $138,000 for the three months ended March 31, 2013 and 2012, respectively.

Financing Activities

Net cash provided by financing activities was $9. 9 million and $50.3 million for the three months ended March 31, 2013 and 2012, respectively, summarized as follows:

(In millions)	Three Months Ended March 31, 2013	2012
Financings pursuant to common stock offerings	$ –	$ 42.1
Issuance of long-term debt, net of expenses	9.9	–
Financings under the ATM Program	–	1.5
Exercise of warrants	–	6.7
Cash flows from financing activities, net	$ 9.9	$ 50.3

The following sections provide a more detailed discussion of our available financing facilities.

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 an earlier shelf registration statement that was declared effective by the SEC on June 21, 2008. As of March 31, 2013, $71 million remained unissued under the 2011 Universal Shelf.

At-the-Market Programs (ATM Program)

On February 11, 2013, we entered into an At-the-Market Equity Offering Sales Agreement (ATM Program) with Stifel pursuant to which Stifel, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell up to a maximum of $25 million of our common stock over a three-year period. We are not required to sell any common stock at any time during the term of the ATM Program. If we issue a sale notice to Stifel, we may designate the minimum price per share at which our common stock may be sold and the maximum number of shares that Stifel is directed to sell during any selling period. As a result, prices are expected to vary as between purchasers and during the term of the offering. Stifel may sell shares by any method deemed to be an "at-the-market" equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, which may include ordinary brokers' transactions on The Nasdaq Capital Market, or otherwise at market prices prevailing at the time of sale or prices related to such prevailing market prices, or as otherwise agreed by Stifel and us. The shares to be offered under the ATM Program are registered under the 2011 Universal Shelf.

Either party may suspend the ATM Program by notice to the other party. The ATM Program will terminate upon the earliest of: (1) the sale of all shares of common stock issuable thereunder, (2) February 11, 2016 or (3) other termination in accordance with the terms of the related agreement. Either party may terminate the ATM Program at any time upon written notification to the other party in accordance with the related agreement.

We have agreed to pay Stifel a commission equal to 3.0% of the gross sales price of shares sold pursuant to the ATM Program. With the exception of expenses related to the shares of common stock, Stifel will be responsible for all of its own costs and expenses incurred in connection with the ATM Program.

Committed Equity Financing Facility (CEFF)

The 2010 CEFF Stock Purchase Agreement originally provided for the lesser of up to 2.1 million shares or a maximum of $35 million, and expires on June 11, 2013. As of March 31, 2013, there were 1.1 million shares remaining under the 2010 CEFF, subject to a maximum of $32.3 million. The remaining shares issuable under the 2010 CEFF are registered pursuant to the 2011 Universal Shelf. Based on the closing market price of our common stock on May 1, 2013 ($1.68) and assuming that all available shares are issued, the potential availability under our CEFF is approximately $1.7 million. 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 2012 Form 10-K for a detailed description of our CEFF, including the covenants and conditions that we must meet to use the CEFF.

We have not utilized the 2010 CEFF since November 2011.

Loan Facility with Deerfield

On February 13, 2013, we entered into a secured loan facility with affiliates of Deerfield Management Company, L.P. (Deerfield) for up to $30 million in financing in 2013 (Deerfield Facility). Deerfield advanced to us $10 million upon execution of the agreement and agreed to advance an additional $20 million, subject to certain conditions, on or about the date of the first commercial sale of SURFAXIN drug product (Milestone Date), provided that the first commercial sale occurs on or before December 31, 2013. The loan may be prepaid in whole or in part without penalty at any time. In addition, the principal amount of the loan may be reduced to the extent that a holder of the notes elects to apply a portion of the principal amount outstanding to satisfy the exercise price of related Warrants (see below) upon exercise of all or a portion of the Warrants.

The principal amount of the loan is payable in equal annual installments on the fourth, fifth and sixth anniversaries of the facility agreement, provided that the amounts payable on the fourth and fifth anniversaries of the facility agreement may be deferred for one year if we achieve certain revenue or market capitalization targets (milestones). *See*, "– Note 6, Long-term Debt – Loan Facility with Deerfield," to the Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q, for a description of the applicable milestones. If the milestones are achieved in each year, payment of the principal amount could be deferred until the sixth anniversary date of the loan on February 13, 2019.

Any amounts received under the Deerfield Facility will accrue interest at a rate of 8.75%, payable quarterly in cash. The facility agreement contains customary terms and conditions but does not require us to meet minimum financial and revenue performance covenants. In connection with each advance, Deerfield has received and may receive a transaction fee equal to 1.5% of any amount disbursed. The facility agreement also contains various representations and warranties and affirmative and negative covenants customary for financings of this type, including restrictions on our ability to incur additional indebtedness and grant additional liens on its assets. In addition, all amounts outstanding under the Deerfield Facility may become immediately due and payable upon (i) an "Event of Default," as defined in the facility agreement, in which case Deerfield would have the right to require us to repay the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the occurrence of certain events as defined in the facility agreement, including, among other things, the consummation of a change of control transaction or the sale of more than 50% of the Company's assets (a Major Transaction).

In connection with the execution of the Deerfield Facility and receipt of the initial disbursement of $10 million, we issued to Deerfield warrants to purchase an aggregate of 2,340,000 shares of our common stock at an exercise price of $2.81 per share of common stock, representing a 24% premium to the closing price of our common stock on The Nasdaq Capital Market on the immediately preceding trading day. If the Milestone Date, as defined in the facility agreement, occurs, upon disbursement of the additional $20 million loan under the facility agreement, we will issue warrants to purchase an additional 4,660,000 shares of our common stock at an exercise price of $2.81 per share of common stock (together with the warrants in the preceding sentence, the "Warrants"). There can be no assurance that the Milestone Date will occur. The number of shares of common stock into which a Warrant is exercisable and the exercise price of any Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock.

Each Warrant issued under the Deerfield Facility will expire on the sixth anniversary of the facility agreement and contains certain limitations that generally prevent the holder from acquiring shares upon exercise of a Warrant that would result in the number of shares beneficially owned by it to exceed 9.985% of the total number of shares of common stock then issued and outstanding. The holder of a Warrant may exercise all or a portion of the Warrant either for cash or on a cashless basis. In connection with a Major Transaction, as defined in the Warrants, to the extent of consideration payable to stockholders in cash in connection with such Major Transaction, the holder may have the option to redeem the Warrant or that portion of the Warrant for cash in an amount equal to the Black-Scholes value (as defined in the Warrant) of the Warrant or that portion of the Warrant redeemed. In addition, in connection with a Major Transaction, to the extent of any consideration payable to stockholders in securities, or in the event of an Event of Default, the holder may have the option to exercise the Warrant and receive therefor that number of shares of Common Stock that equals the Black-Scholes value of the Warrant or that portion of the Warrant exercised. Prior to the holder exercising the Warrant for shares in such transactions, the Company may elect to terminate the Warrant or that portion of the Warrant and pay the holder cash in an amount equal to the Black-Scholes value of the Warrant.

We have recorded the loan as long-term debt at its face value of $10.0 million less debt discounts and issuance costs consisting of (i) $3.8 million, representing the Black-Scholes option-pricing model fair value of 2,340,000 Warrants issued upon the advance of the $10 million initial disbursement; and (ii) a $150,000 transaction fee. The discount is being accreted to the $10.0 million loan over its term using the effective interest method. The Warrants are derivatives that qualify for an exemption from liability accounting provided for in ASC 815 and have been classified as equity.

Long-term debt as of March 31, 2013 consists solely of amounts due under the Deerfield Facility as follows:

Note Payable	$ 10,000
Unamortized discount	(3,917)
Long-term debt, net of discount	$ $ 6,083

Contractual Obligations and Commitments

Future payments due under contractual obligations at March 31, 2013 are as follows:

(in thousands)	2013	2014	2015	2016	2017	There-after	Total
Operating lease obligations	$ 1,074	$ 1,087	$ 949	$ 934	$ 935	$ 158	$ 5,137
Deerfield Loan Facility[1]	-	-	-	-	3,333	6,667	10,000
Equipment loan obligations [1]	69	79	69	–	–	–	217
Total	$ 1,143	$ 1,166	$ 1,018	$ 934	$ 4,268	$ 6,825	$ 15,354

[1] *See*, "Note 6 – Long-Term Debt," to the Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash and cash equivalents. We place our investments with high quality issuers and, by policy, we have limits as to the amount of credit exposure to any one issuer. We do not hedge interest rate or currency exchange exposure and do not use derivative financial instruments for speculation or trading purposes. We classify highly liquid investments purchased with a maturity of three months or less as "cash equivalents." Loans under our Deerfield Facility have a fixed interest rate of 8.75%. Because of the fixed rate, a change in market interest rates would not have a material impact on interest expense associated with the loan.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Our management, including our President and Chief Executive Officer and Chief Financial Officer (principal executive officer and 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 President and Chief Executive Officer and Chief Financial Officer has 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 President and Chief Executive Officer and 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 President and Chief Executive Officer and 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 controls 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, 2013, 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

Investing in our securities involves risks. In addition to the other information in this quarterly report on Form 10-Q, stockholders and potential investors should carefully consider the risks and uncertainties discussed in the section "Item 1A. Risk Factors" in our 2012 Form 10-K, as supplemented by the risks and uncertainties discussed below and elsewhere in this Quarterly Report on 10-Q. If any of the risks and uncertainties set forth below or in our 2012 Form 10-K actually materialize, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment. The risks and uncertainties set forth below and discussed elsewhere in this Quarterly Report on Form 10-Q and described in our 2012 Form 10-K are not the only ones that may materialize. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations.

The recent response in April 2013 by the United States (U.S.) Food and Drug Administration to a submission that we made with respect to an analytical chemistry method used to assess SURFAXIN® drug product's conformance to specifications that required improvement and related updated product specifications has caused us to further delay the commercial availability of SURFAXIN, which could have a material adverse effect on our ability to execute our business strategy and fund our operations.

In October 2012, we announced that, during a review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, we had determined that one of our analytical chemistry methods used to assess SURFAXIN drug product's conformance to specifications required improvement and that an update to product specifications would be necessary. Thereafter, we communicated our findings to the FDA, improved and validated the analytical method, and submitted updated product specifications to the FDA. We anticipated that, if the FDA agreed with our submission, the availability of SURFAXIN drug product would be delayed until the second quarter of 2013. In April 2013, we received a response from the FDA that requested clarification and provided recommendations regarding the recently updated product specifications for SURFAXIN. The FDA correspondence included a request for specific information intended to clarify certain aspects of the updated product specifications and the revalidated analytical chemistry method, including recommendations regarding how the product specifications should be documented and notated; a specific recommendation for the upper limit of a single product specification, which we can readily accept; a request for two existing and readily available documents related to the improved analytical chemistry method; and a request for supporting data using the recently improved and revalidated analytical chemistry method that is being generated from recent SURFAXIN batches. We plan to provide our response to the FDA by early June. FDA procedure provides up to four months for it to review a submission such as ours. Based on the anticipated time required to respond and await confirmation from the FDA, we anticipate that if our plan is successful and confirmed by the FDA within this timeline, we expect to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013.

We currently believe that we will succeed within the time outlined above, there can be no assurance that we will be successful and complete the work necessary to support our response to the FDA within the timeline outlined above. We may be unable to manufacture and release SURFAXIN drug product to our revised updated product specifications, if at all, to generate data for inclusion in our response to the FDA and for commercial sale in the fourth quarter of 2013. The FDA may not accept our submission, or may require additional information that would require additional time, or may not respond within the time set forth in the FDA’s guidelines (four months for submissions of the type we plan to submit). Moreover, we may identify unforeseen problems that have not yet been discovered that could adversely affect our plans. In addition, there is a risk that the FDA may determine to conduct a facility inspection to review our approach and response to dealing with the issues identified in our original submission. Any failure to satisfy any issues raised by the FDA could significantly delay, or preclude outright, our gaining agreement on acceptable updated product specifications, or could result in an action by the FDA to restrict our ability to commercialize some or all of our products, which could potentially delay or prevent the commercial availability of SURFAXIN drug product.

Although we have made a strategic decision to retain our commercial and medical affairs organizations during this period, there can be no assurance that we will be able to retain our commercial and medical affairs personnel until such time as we are able to effect the commercial introduction of SURFAXIN, or attract additional personnel when needed to support the commercial introduction of SURFAXIN and AFECTAIR®, our disposable, aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal or pediatric intensive care units. There also can be no assurance that our efforts with respect to SURFAXIN will be successful and completed within our anticipated timeline, if at all.

We will require significant additional capital to continue our operations, pay our debt service, and continue our planned research and development activities. Moreover, such additional financing could result in substantial dilution to our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

We will need substantial additional funding to support our commercial operations and our ongoing research and development activities and our operations. As of March 31, 2013, we have an accumulated deficit of approximately $447.4 million and we expect to continue to incur significant, increasing operating losses over the next several years. To date, we have generated capital to support our activities primarily from equity financings, research grants, collaboration agreements, and investments. As of March 31, 2013, we had cash and cash equivalents of approximately $26.4 million and approximately $7 million of accounts payable and accrued expenses and $10 million of long-term debt under the Deerfield Facility. As a result of the delay in commercial availability of SURFAXIN drug product from the second quarter potentially to the fourth quarter of 2013, we have assessed and made adjustments to our strategic plan. Since we expect a moderate delay of up to six months, we have determined to maintain our U.S. commercial and medical affairs capabilities and plan to continue investments in activities necessary to potentially advance our AEROSURF® program and initiate a planned phase 2 clinical program in the fourth quarter of 2013. We also have adopted a plan intended to conserve cash resources by pacing certain other investments in our operations and commercial and development programs through the fourth quarter of 2013. To execute this business strategy and fund our operations, we will require significant additional infusions of capital until such time as the net revenues from SURFAXIN and AFECTAIR, from potential strategic alliance and collaboration arrangements and from other sources are sufficient to offset our cash flow requirements.

In February 2013, we entered into an agreement (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield), pursuant to which Deerfield advanced $10 million to us and has agreed to advance an additional $20 million, subject to certain conditions, on or about the date of the first commercial sale of SURFAXIN, provided that the first sale occurs not later than December 31, 2013. As a result of the recent delay, our access to the second disbursement under the Deerfield Facility has also been delayed and, if the recent delay extends beyond December 31, 2013, our ability to access the $20 million under the Deerfield Facility will expire, which could have a material adverse effect on our business, operations and financial condition.

Also in February 2013, we entered into an At-the-Market Equity Offering Sales Agreement with Stifel, pursuant to which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell over a three-year period up to a maximum of $25 million of our common stock through the ATM Program. We are not required to sell any shares at any time during the term of the ATM Program. We will pay Stifel a commission for each transaction equal to 3% of the gross proceeds. We intend to use the net proceeds from the ATM Program, if any, to meet our working capital requirements to execute our business plans. There can be no assurance that we will issue any Shares pursuant to the ATM Program.

In addition to potential funding that may be available under the Deerfield Facility, the ATM Program, and our 2010 CEFF (which is subject to certain conditions and will expire on June 11, 2013), we will require significant infusions of capital to fund the anticipated increase in our cash outflows as we continue to invest in our commercial and medical affairs organization and execute the commercial introduction of our approved products, as well as our research and development programs. In addition to the recent delay in commercial availability of SURFAXIN, even if we succeed and both SURFAXIN drug product and AFECTAIR are introduced commercially as planned, given the time required to secure formulary acceptance of SURFAXIN at our target hospitals and acceptance of a new product, we expect our revenues from SURFAXIN and AFECTAIR to be modest in the first 12-18 months and then increase over time as our products gain hospital acceptance. Our investments in our operations, debt service and development programs are expected to outpace the rate at which we may generate revenues for several years. We will require infusions of capital until such time as our revenues from SURFAXIN and AFECTAIR are sufficient to fund our ongoing activities.

Anticipating a delay of up to six months, we have reviewed our expenses and plan to maintain our commercial and medical affairs capabilities and continue to invest in the AEROSURF development program, which will limit our ability to significantly reduce our cash outflows. However, we plan to pace certain other investments that we otherwise would have made, which could adversely impact our plans and put at risk our ability to meet our objectives. If the recent delay extends beyond December 31, 2013, our ability to access the $20 million under the Deerfield Facility will expire, which could have a material adverse effect on our business, operations and financial condition. If for any reason, we experience a longer delay in the commercial introduction of SURFAXIN than currently anticipated, depending upon the length of delay and the underlying cause, we believe that such events could have a material adverse impact on our ability to raise additional capital, whether through use of our ATM Program or otherwise. If the delay were not of a long duration, we believe that our fundamental strategy could remain intact and we would continue to manage our cash resources closely until such time as we have resolved our issues and reinitiated our efforts to effect the commercial introduction of SURFAXIN. If any delay were extended for longer periods of time and we are unable to raise additional capital for any reason, we would have to reassess our business strategy and the level of our investments in all categories and would have to consider fundamental changes to our business plans.

If we are unable to successfully raise sufficient additional capital, we will likely not have sufficient cash flows and liquidity to fund our business operations as presently contemplated beyond the fourth quarter 2013. In that event, we may be forced to further limit development of many, if not all, of our programs and consider other means of creating value for our stockholders, such as outsourcing certain of our activities and licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop or commercialize ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

Even if we are successful in generating revenues from the sale of approved products in the future, we will likely not have sufficient cash flow and liquidity to fund our research and development programs and will require additional capital to support these efforts. We would prefer to accomplish these objectives through strategic alliances and collaboration arrangements. We are seeking strategic alliances to support the development of AEROSURF and, if approved, to commercialize these product candidates in the European Union (EU) and other markets outside the United States (U.S.). We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially other major markets. If we are unable to successfully raise the necessary additional capital, we will likely not have sufficient cash flow and liquidity to fund our research and development programs and may be forced to further limit investments in our development programs, which could have a material adverse effect on our business. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" in our 2012 Form 10-K and in "Part 1, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Quarterly Report on Form 10-Q.

Moreover, depending on conditions in the global financial markets, we may face significant challenges accessing the capital markets at a time when we would like or require, and at an increased cost of capital. Except for the potential second disbursement of funds under our Deerfield Facility, our ATM Program and our CEFF, which has available approximately 1.1 million shares and expires on June 11, 2013, we currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. In any such event, the market price of our common stock may decline. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could delay new product development and clinical trial plans.

Even after completing our Deerfield Facility, we will need to obtain additional capital to successfully commercialize our approved products and develop our products under development, including AEROSURF and SURFAXIN LS, and continue our other research and development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to execute our business plans, including to effect the commercial introduction of SURFAXIN and AFECTAIR, execute our development plans for AEROSURF and our lyophilized KL_4 surfactant, including our planned phase 2 clinical program, and potentially SURFAXIN LS, and continue our research and development programs to advance our product pipeline in the future. Our plans had included receipt of a second $20 million disbursement under the Deerfield Facility upon the first commercial sale of SURFAXIN drug product in the second quarter 2013. As a result of the delay in commercial availability of SURFAXIN, from the second quarter potentially to the fourth quarter of 2013, the second Deerfield disbursement is also delayed. If this delay extends beyond December 31, 2013, our ability to access the $20 million under the Deerfield Facility will expire. At the present time, we believe that our existing cash and cash equivalents, including net proceeds from the initial disbursement under the Deerfield Facility, will be sufficient to fund our operations into the fourth quarter of 2013. We will need to raise additional funds to continue our operations. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of our products or our research and development programs. We also could be required to:

- seek collaborators for one or more of our development programs for territories that we had planned to retain or on terms that are less favorable than might otherwise be available; and/or

- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

We plan to seek additional sources of non-dilutive financing, including potentially a capital financing facility, to fund a portion of our expenses. However, such facilities may not be available, if at all, on terms that are favorable or acceptable to us. If we are unable to secure such financing, we may seek additional capital from the public markets, which could have a dilutive impact on our stockholders and the issuance, or even potential issuance, of shares could have a negative effect on the market price of our common stock.

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.

As we prepared for the commercial introduction of SURFAXIN, we implemented a plan to hire additional qualified personnel to support (i) the commercial introduction of SURFAXIN and AFECTAIR, and (ii) the advancement of our AEROSURF and SURFAXIN LS development programs. In particular, we have established our field-based sales and marketing and medical affairs organizations, and began enhancing our regulatory affairs, quality control and assurance and administrative capabilities. 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.

We have recently entered into employment agreements with five executive officers, including the President and Chief Executive Officer 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. These agreements expire on March 31, 2015, subject to automatic renewal for additional one-year periods, unless a party provides notice of non-renewal at least 90 days in advance. In addition, we recently entered into new agreements with five other officers that also expire on March 31, 2015. 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 commercial introduction of our approved products and initiate our phase 2 clinical program for our AEROSURF development program, we need to attract and retain highly-qualified personnel to join our management, commercial, medical affairs and development teams, although there can be no assurances that we will be successful in that endeavor. We may be unable to attract and retain necessary executive talent. Moreover, the equity incentives in the form of options 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.

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.

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

During the three months ended March 31, 2013, we issued 7,500 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during 2013. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(2) of the Act.

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 7, 2013

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

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
3.1	Amended and Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery), as amended by a Certificate of Amendment to the Restated Certificate of Incorporation of Discovery filed on December 27, 2010, as further amended by a Certificate of Amendment to the Restated Certificate of Incorporation of Discovery filed on October 3, 2011	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report for the quarter ended September 30, 2011, as filed with the SEC on November 14, 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.

Exhibit No.	Description	Method of Filing
4.8	Form of Series I Warrant to Purchase Common Stock issued on June 22, 2010 (Five-Year Warrant)	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 17, 2010.
4.9	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 Series I Warrant to Purchase Common Stock issued on February 22, 2011 (Five-Year Warrant)	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.
4.11	Form of Series II Warrant to Purchase Common Stock 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.
4.12+	Form of Warrant issued to Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P. (collectively, Deerfield) under a Facility Agreement dated as of February 13, 2013 between Discovery and Deerfield (Deerfield Facility)	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
4.13	Form of Notes issued to Deerfield evidencing loan under Deerfield Facility	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.1+	Facility Agreement, dated as of February 13, 2013, between Discovery and Deerfield as lenders	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.2	Registration Rights Agreement, dated as of February 13, 2013, between Discovery and Deerfield as lenders	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.3	Security Agreement, dated as of February 13, 2013, between Discovery and Deerfield as secured parties	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.4	At-the-Market Equity Offering Sales Agreement between Discovery and Stifel, Nicolaus & Company, Incorporated, dated February 11, 2013	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 13, 2013.
10.5	Second Amendment to Lease Agreement dated as of January 3, 2013, by and between Discovery and TR Stone Manor Corp.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 8, 2013.
10.6	Indemnification Agreement dated as of January 3, 2013, between the Company and Joseph M. Mahady	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 4, 2013.

Exhibit No.	Description	Method of Filing
10.7*	Employment Agreement dated as of April 1, 2013 between Discovery and John G. Cooper	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 2, 2013.
10.8*	Employment Agreement dated as of April 1, 2013 between Discovery and Thomas F. Miller	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 2, 2013.
31.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith.
101.1	The following consolidated financial statements from the Discovery Laboratories, Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of March 31, 2013 (unaudited) and December 31, 2012, (ii) Statements of Operations (unaudited) for the three ended March 31, 2013 and March 31, 2012, (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2013 and March 31, 2012, and (v) Notes to consolidated financial statements.	
101.INS	Instance Document	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

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

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

Exhibit 31.1

CERTIFICATIONS

I, John G. Cooper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Discovery Laboratories, Inc. (the “Company);

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 Company as of, and for, the periods presented in this report;

4. I am 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 Company 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 Company, 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 Company’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 Company’s internal control over financial reporting that occurred during the Company’s most recent fiscal quarter (the Company’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company’s auditors and the audit committee of the Company’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 Company’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 Company’s internal control over financial reporting.

Date: May 7, 2013

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

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, the undersigned officer 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, 2013 (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 7, 2013

/s/ John G. Cooper
John G. Cooper
President and Chief Executive Officer and Chief Financial Officer
(Principal Executive and 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.