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

FORM 10-Q

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

For the quarterly period ended June 30, 2014

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	x
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 x

As of July 31, 2014, 85,206,616 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

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PART I - FINANCIAL INFORMATION

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only estimates 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 such terms as "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 during which our existing resources are expected to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans, and our expectations related to the commercialization of SURFAXIN® and our expectations, timing and anticipated outcomes of development activities, potential regulatory filings and plans to secure marketing authorization for our products under development, starting with AEROSURF®; our research and development programs, including planning for development activities, anticipated timing and design of clinical trials and potential development milestones, for our KL4 surfactant pipeline product candidates and our capillary aerosol generator (CAG) for delivery of aerosolized medications; plans for the manufacture of drug products, active pharmaceutical ingredients (APIs) and materials, and medical devices and related components; and plans regarding potential strategic alliances and other collaborative arrangements to develop, manufacture and market our products.

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

- the risk that we will require in the near term, but may be unable to secure, significant additional capital to continue our operations, fund our debt service and support our research and development activities, including expensive and time-consuming clinical trials, until such time, if ever, that our revenues from all sources are sufficient to offset our cash outflows. To the extent that we raise such capital through additional financings, such additional financings could result in equity dilution;

- the risk that, if we fail to successfully commercialize SURFAXIN and if we are unable to achieve revenues over the next several years that are consistent with our expectations, it may be more difficult to secure the additional capital we will require when needed, if at all, whether from strategic alliances or other sources, to continue our commercial and medical affairs activities, as well as our research and development programs, and our operations would be impaired, which ultimately could have a material adverse effect on our business, financial condition and results of operations;

- risks relating to the ability of our sales and marketing organization to effectively introduce SURFAXIN in the United States (U.S.) and, if approved, our other product candidates, in a timely manner, if at all; and that we may not succeed in developing sufficient market awareness of our products or that our product candidates may not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;

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

- the risk that the initial and later phases of our AEROSURF clinical program may be interrupted, delayed, or fail, which will harm our business;
- the risk that we and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;
- the risk that we may not succeed in implementing our long-term manufacturing strategy to assure continuity of SURFAXIN commercial drug product supply, which may affect our ability to maintain sufficient supplies of SURFAXIN commercial drug product;
- risks relating to the transfer of our manufacturing technology to contract manufacturing organizations (CMOs) and assemblers;
- risks relating to our and our CMOs' ability to manufacture our KL4 surfactant, in liquid and lyophilized dosage forms, which require precise methods of manufacture in an aseptic manufacturing environment, as well as complex analytical and quality control release and stability methodologies, for both commercial and research and development activities;
- risks relating to our and our CMOs' ability to develop and manufacture combination drug/device products based on our CAG technology, for preclinical and clinical studies of our product candidates and, ultimately if approved, for commercialization;
- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems in manufacturing our KL4 surfactant drug products and the APIs used in the manufacture of our drug products, CAG devices and other materials on a timely basis or in an amount sufficient to support our needs;
- risks relating to our plans to potentially 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;
- 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, including development of our lyophilized KL4 surfactant, and, if approved, commercialization of AEROSURF in markets outside the U.S.; support the commercialization of SURFAXIN in countries where regulatory approval is facilitated by the information contained in the SURFAXIN new drug application (NDA) approved by the FDA; and potentially support the development and, if approved, commercialization, of our other pipeline products;
- risks relating to our pledge of substantially all of our assets to secure our obligations under our loan facility (Deerfield Loan) with affiliates of Deerfield Management Company, L.P., 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 investment; and
- other risks and uncertainties as detailed in “Risk Factors” in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 17, 2014, and our other filings with the SEC and any amendments thereto, and in the documents incorporated by reference in this report.

Pharmaceutical, biotechnology and medical technology companies have suffered significant setbacks conducting clinical trials, even after obtaining promising earlier preclinical and clinical data. Moreover, data obtained from 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 because of new information, future events or otherwise.

Trademark Notice

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
Consolidated Balance Sheets

(in thousands, except per share data)

	June 30, 2014 (Unaudited)	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 65,557	$ 86,283
Accounts receivable	41	67
Inventory, net	443	112
Prepaid expenses and other current assets	443	777
Total current assets	66,484	87,239
Property and equipment, net	2,178	1,656
Restricted cash	325	325
Other assets	487	97
Total assets	$ 69,474	$ 89,317
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,507	$ 1,433
Accrued expenses	5,951	4,785
Deferred revenue	105	139
Common stock warrant liability	3,224	5,425
Equipment loans, current portion	75	73
Total current liabilities	10,862	11,855
Long-term debt, $30,000 net of discount of $10,736 at June 30, 2014 and $11,646 at December 31, 2013	19,264	18,354
Equipment loans, non-current portion	28	69
Other liabilities	114	538
Total liabilities	30,268	30,816
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 250,000,000 and 150,000,000 shares authorized; at June 30, 2014 and December 31, 2013, respectively; 85,227,508 and 84,659,111 shares issued at June 30, 2014 and December 31, 2013, respectively; 85,206,616 and 84,638,219 shares outstanding at June 30, 2014 and December 31, 2013, respectively	85	85
Additional paid-in capital	544,224	541,420
Accumulated deficit	(502,049)	(479,950)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total stockholders' equity	39,206	58,501
Total liabilities & stockholders' equity	$ 69,474	$ 89,317

See notes to consolidated financial statements.

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Revenues:				
Product sales	$ 42	$ –	$ 70	$ –
Grant revenue	1,051	182	1,054	254
	1,093	182	1,124	254
Expenses:				
Cost of product sales	731	–	1,512	–
Research and development	6,858	6,863	12,448	15,335
Selling, general and administrative	4,446	4,129	8,869	8,349
	12,035	10,992	22,829	23,684
Operating loss	(10,942)	(10,810)	(21,705)	(23,430)
Change in fair value of common stock warrant liability	1,448	2,525	1,826	2,686
Other income / (expense):				
Interest and other income	2	1	4	1
Interest and other expense	(1,131)	(343)	(2,224)	(520)
Other income / (expense), net	(1,129)	(342)	(2,220)	(519)
Net loss	$ (10,623)	$ (8,627)	$ (22,099)	$ (21,263)
Net loss per common share				
Basic	$ (0.12)	$ (0.18)	$ (0.26)	$ (0.46)
Diluted	$ (0.14)	$ (0.22)	$ (0.28)	$ (0.50)
Weighted average number of common shares outstanding				
Basic	85,061	49,135	84,766	46,411
Diluted	85,882	49,866	86,111	47,773

See notes to consolidated financial statements.

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

(in thousands)

	Six Months Ended June 30,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (22,099)	$ (21,263)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	371	364
Provision for excess inventory	1,465	–
Stock-based compensation and 401(k) Plan employer match	1,975	1,489
Fair value adjustment of common stock warrants	(1,826)	(2,686)
Amortization of discount on long-term debt	909	177
Changes in:		–
Inventory	(2,196)	159
Accounts receivable	26	–
Prepaid expenses and other current assets	334	101
Accounts payable	74	753
Accrued expenses	1,166	580
Deferred revenue	(34)	–
Other assets	–	(107)
Other liabilities	(423)	(10)
Net cash used in operating activities	(20,258)	(20,443)
Cash flows from investing activities:		
Purchase of property and equipment	(883)	(120)
Net cash used in investing activities	(883)	(120)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	–	15,110
Proceeds from issuance of long-term debt, net of expenses	–	9,850
Proceeds from exercise of common stock options	31	1
Proceeds from exercise of common stock warrants	423	–
Repayment of equipment loans	(39)	(37)
Net cash provided by financing activities	415	24,924
Net decrease in cash and cash equivalents	(20,726)	4,361
Cash and cash equivalents – beginning of period	86,283	26,892
Cash and cash equivalents – end of period	$ 65,557	$ 31,253
Supplementary disclosure of cash flows information:		
Interest paid	$ 1,305	$ 336

See notes to consolidated financial statements.

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 and devices potentially to enable efficient delivery of our aerosolized KL_4 surfactant. We believe that our proprietary technologies may 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.

We are initially focused on improving 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. RDS is the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU) and can result in long-term respiratory problems, developmental delay and death. Our first KL_4 surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL_4 surfactant in liquid form, and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States (U.S.). SURFAXIN has been commercially available in the U.S. since November 2013.

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may result in serious respiratory conditions and other complications. To avoid such complications, many neonatologists initially treat infants with less severe RDS by less invasive means, typically nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of premature infants on nCPAP will not respond well (an outcome referred to as nCPAP failure) and thereafter may require endotracheal intubation, mechanical ventilation, and delayed surfactant therapy. Since neonatologists currently cannot predict which infants will experience nCPAP failure, neonatologists are faced with difficult choices in treating infants with less severe RDS. This is because the medical outcomes for those infants who experience nCPAP failure and receive delayed surfactant therapy may be less favorable than the outcomes for infants who receive surfactant therapy in the first hours of life.

AEROSURF® is our investigational combination drug/device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). AEROSURF potentially will enable administration of aerosolized KL_4 surfactant to premature infants supported with nCPAP, without invasive intubation and mechanical ventilation. By enabling delivery of our KL_4 surfactant using less invasive procedures, we believe that AEROSURF may address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated. We are currently conducting a phase 2a clinical trial for AEROSURF for the treatment of RDS in premature infants, for which results are expected in the fourth quarter of 2014, and are initiating activities to prepare for a phase 2b clinical trial, with results expected in the second half of 2015.

We are also developing a lyophilized (freeze-dried) dosage form of our KL_4 surfactant that is stored as a powder and reconstituted 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 initially developing this dosage form for use in our AEROSURF development program. We are also planning to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of our KL_4 surfactant under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the U.S. and potentially in other markets.

To support the commercial introduction of SURFAXIN in the U.S. and our other KL_4 surfactant pipeline products, if approved, we have our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL_4 surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL_4 surfactant. In addition, we recognize that our commercial and medical affairs team could potentially support introductions of other synergistic pipeline products, including products owned or developed by third parties for the NICU/PICU. To that end, we would consider potential transactions focused on securing commercial rights to such synergistic products, including in the form of product acquisitions, in-licensing agreements or distribution, marketing or co-marketing arrangements.

In the future, we expect that we may be able to leverage the information, data and know-how that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a product pipeline to address serious critical care respiratory conditions in larger children and adults in pediatric and adult intensive care units (PICUs and ICUs), including potentially acute lung injury (ALI), chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). At the present time, however, we are focusing our resources primarily on the commercial introduction of SURFAXIN and development of AEROSURF through phase 2 clinical trials. Once we have advanced these objectives, we expect to be in a better position to assess the potential of other development programs to address the critical care needs of patients in the PICU and ICU.

Note 2 – Liquidity Risks and Management's Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, and, more recently, commercialization and medical affairs 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, debt facilities, strategic alliances, the use of committed equity financing facilities (CEFFs) and at-the-market (ATM) equity programs, and capital equipment financings.

As of June 30, 2014, we had cash and cash equivalents of $65.6 million and long-term debt of $30 million ($19.3 million net of discount) under our Deerfield Loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 7 – "Deerfield Loan") . Before any additional financings, including under our ATM Program (*see*, Note 11 - "At-the-Market Program (ATM Program)," to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2013 (2013 Form 10-K)), we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the third quarter of 2015.

For the next several years, we expect that our cash outflows for marketing, commercial and medical activities, development programs, operations and debt service will outpace the rate at which we may generate revenues. To execute our business strategy, pay debt obligations and fund our operations over the next several years, we will require significant additional infusions of capital until such time as the net revenues from the sale of approved products and from other sources are sufficient to offset our cash flow requirements. While we currently intend to retain all rights and commercialize our approved products in the U.S. by ourselves, an important priority for us is to identify strategic transactions that could provide additional capital and strategic resources to support the continued development and commercial introduction of our RDS products in markets outside the U.S. For our AEROSURF development program, we seek a significant strategic alliance that potentially could provide development, regulatory and commercial market expertise, and, if approved, support the commercial introduction of AEROSURF in the EU and other selected markets outside the U.S. Such alliances typically also would provide financial resources, in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. To advance SURFAXIN in markets outside the U.S. where regulatory marketing authorization is facilitated by the information contained in our new drug application (NDA) approved by the FDA, we would consider various financing or collaboration arrangements that could potentially provide regulatory expertise, support the commercial introduction of SURFAXIN in markets outside the U.S., and a sharing of revenues. Such countries could potentially include those in Latin America, North Africa and the Middle East. To secure the necessary capital, we also plan to consider other public and private equity offerings, including under our ATM Program, which currently may allow for the sale of up to approximately $23 million of our commons stock, as well as other financing transactions, such as secured equipment financing facilities or other similar transactions.

Our future capital requirements will depend upon many factors, primarily our efforts to (i) execute the commercial introduction of SURFAXIN in the U.S.; (ii) advance the AEROSURF development program to completion of the phase 2 clinical trials as planned in the second half of 2015; (iii) assure long-term continuity of supply for both our commercial and lyophilized KL_4 surfactant drug product, potentially with CMOs and/or at our manufacturing facility in Totowa, NJ (Totowa Facility); and (iv) secure one or more strategic alliances or other collaboration arrangements to support our development programs and commercialization of our approved products, if any, in markets outside the U.S. We believe that we will be better positioned to enter into a significant strategic alliance if we are successful in advancing the commercial introduction of SURFAXIN and completing and obtaining encouraging results from the AEROSURF phase 2 clinical program within our anticipated time.

Although we currently believe that we will be able to successfully execute our business strategy as planned, there can be no assurance that any of our approved products, including SURFAXIN, will be commercially viable or that we will be able to execute our long-term manufacturing plan, that our AEROSURF development program will be successful within our anticipated time frame, if at all, that we will be able to secure regulatory marketing authorization for AEROSURF and our other KL4 surfactant product candidates, in the U.S. and other markets, that the ATM Program will be available when needed, if at all, or that we will be able to obtain additional capital when needed and on acceptable terms. We will require significant additional capital to sustain operations, satisfy debt obligations, and complete product development and execute the commercial introduction of our KL4 surfactant product candidates, if approved. Failure to secure the necessary additional capital when needed would have a material adverse effect on our business, financial condition and results of operations. Even if we succeed in raising additional capital and developing and subsequently commercializing our product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of June 30, 2014, we had outstanding warrants to purchase approximately 14.0 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, warrants to purchase 7 million shares were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share. The Deerfield Warrants may be exercised for cash or on a cashless basis. In lieu of paying cash upon exercise, the holders also may elect to reduce the principal amount of the Deerfield Loan in an amount sufficient to satisfy the exercise price of the Deerfield Warrants. In addition to the Deerfield Warrants, we have outstanding warrants issued in February 2011 to purchase approximately 4.6 million shares of common stock that 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 currently have an exercise price of $1.50 per share and expire in February 2016. Although we believe that, in the future, we may receive 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 would make exercise of outstanding warrants likely, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. 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.

As of June 30, 2014, 250 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 137.2 million shares of common stock were available for issuance and not otherwise reserved.

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 Form10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete consolidated financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. There have been no changes to our critical accounting policies since December 31, 2013. For a discussion of our accounting policies, *see*, Note 3, “Accounting Policies and Recent Accounting Pronouncements,” to the consolidated financial statements in our 2013 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Inventory

Inventories, which are recorded at the lower of cost or market, include materials, labor, and other direct and indirect costs and are valued at cost using the first-in, first-out method. We capitalize inventories produced in preparation for commercial launch when the related product candidates receive regulatory approval and the related costs will be recoverable through the commercial sale of the product. Costs incurred prior to FDA approval of drug products and registration of medical devices are recorded in our statement of operations as research and development expense. Inventories are evaluated for impairment through consideration of factors such as the net realizable value, lower of cost or market, obsolescence, and expiry. Inventories do not have carrying values that exceed either cost or net realizable value.

We evaluate our expiry risk by evaluating current and future product demand relative to product shelf life. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and hospital ordering practices.

Accrued Severance and Retention Costs

A liability for employee severance and retention benefits is recognized when (1) management has committed to a plan of termination; (2) the plan provides sufficient details, such as the employees affected, amounts to be paid, and expected dates of termination and payment; (3) it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn; and (4) the plan has been communicated to employees. The cost of such benefits are accrued over the remaining service period.

In September 2013, we implemented an employee severance and retention plan for employees at our Totowa Facility to minimize employee turnover and encourage employees to remain with us through any potential plant closing. The plan provides for severance for non-union employees and retention bonuses for management. If we succeed in our efforts to secure longer-term utilization of the Totowa Facility, the severance plan and retention bonuses will remain in effect. The total cash amount expected to be paid for severance and retention under this plan through June 2016, assuming a June 2015 plant closing, is approximately $1.1 million. The plan-related expense for the three and six months ended June 30, 2014 was $0.1 million and $0.3 million, respectively, and is included in research and development expense. The related accrued liability is $0.4 million as of June 30, 2014.

In addition, at the Totowa Facility, there are 13 employees who are subject to a collective bargaining agreement under which they would be eligible to receive severance payments if the Totowa Facility were closed. The related accrued liability is $0.4 million as of June 30, 2014.

Product Sales

Revenues from product sales are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured.

Our products are distributed in the U.S. using a specialty distributor. Under this model, the specialty distributor purchases and takes physical delivery and title of product, and then sells to hospitals. We began the commercial introduction of SURFAXIN in the fourth quarter of 2013 and we currently cannot make a reasonable estimate of future product returns when product is delivered to the specialty distributor. Therefore, we currently do not recognize revenue upon product shipment to the specialty distributor, even though the distributor is invoiced upon product shipment. Instead, we recognize revenue once product has been sold through to the hospital and all revenue recognition criteria have been met. Once product has been delivered to a hospital, the risk of material returns is significantly mitigated. We will begin to recognize revenue at the time of shipment of product to our specialty distributor when we can reasonably estimate expected distributor sales deductions and returns. In developing estimates for sales returns, we consider the shelf life of the product, expected demand based on market data and return rates of other surfactant products.

Product sales are recorded net of accruals for estimated chargebacks, discounts, specialty distributor deductions and returns.

- *Chargebacks*. Chargebacks are discounts that occur when contracted customers purchase directly from our specialty distributor. Contracted customers, which currently consist primarily of Group Purchasing Organizations member hospitals, generally purchase the product at a discounted price. Our specialty distributor, in turn, charges back the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the customer. The allowance for specialty distributor chargebacks is based on known sales to contracted customers.

- *Sales discounts.* Sales discounts are offered to certain contracted customers based upon a customer's historical volume of surfactant product purchases. Customers must enter into a Letter of Participation (LOP) with us to receive sales discounts. Sales discounts are periodically adjusted on a prospective basis based upon the customer's purchases of SURFAXIN, as provided in the LOP. The allowance for sales discounts is based on known sales to contracted customers.

- *Specialty distributor deductions*. Our specialty distributor is offered various forms of consideration including allowances, service fees and prompt payment discounts. Specialty distributor allowances and service fees are provided in our contractual agreement and are generally a percentage of the purchase price paid by the specialty distributor. The specialty distributor is offered a prompt pay discount for payment within a specified period.

- *Returns*. Sales of our products are not subject to a general right of return; however, we will accept product that is damaged or defective when shipped or for expired product up to six months subsequent to its expiry date. Product that has been administered to patients is no longer subject to any right of return.

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.

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. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. For the quarters ended June 30, 2014 and 2013, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 20.9 million and 15.8 million shares, respectively.

In accordance with Accounting Standards Codification (ASC) Topic 260, "*Earnings per Share*," when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of certain warrants classified as derivative liabilities results in an adjustment to the net loss; and the dilutive impact of the assumed exercise of the warrants results in an adjustment to the weighted average common shares outstanding. We utilize the treasury stock method to calculate the dilutive impact of the assumed exercise of the warrants. For the three and six months ended June 30, 2014 and 2013, the effect of the adjustments for warrants issued in February 2011 was dilutive.

The table below provides information pertaining to the calculation of diluted net loss per common share for the periods presented:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Numerator:				
Net loss as reported	$ (10,623)	$ (8,627)	$ (22,099)	$ (21,263)
Less: income from change in fair value of warrant liability	(1,447)	(2,494)	(1,820)	(2,584)
Numerator for diluted net loss per common share	$ (12,070)	$ (11,121)	$ (23,919)	$ (23,847)
Denominator:				
Basic weighted average common shares outstanding	85,061	49,135	84,766	46,411
Dilutive common shares from assumed warrant exercises	821	731	1,345	1,362
Diluted weighted average common shares outstanding	85,882	49,866	86,111	47,773

As of June 30, 2014 and 2013, 16.4 million and 10.8 million shares of common stock potentially issuable upon the exercise of certain stock options and warrants were excluded from the computation of diluted net loss per common share because their impact would have been anti-dilutive.

We do not have any components of other comprehensive income (loss).

Recent accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. generally accepted accounting principles (GAAP) when it becomes effective. The new standard is effective for us in our fiscal year 2017. Early application is not permitted. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

Note 4 – 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 tables below categorize assets and liabilities measured at fair value on a recurring basis for the periods presented:

	Fair Value	Fair value measurement using		
	June 30, 2014	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 65,557	$ 65,557	$ –	$ –
Certificate of Deposit	325	325	–	–
Total Assets	$ 65,882	$ 65,882	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 3,224	$ –	$ –	$ 3,224

	Fair Value	Fair value measurement using		
	December 31, 2013	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 86,283	$ 86,283	$ –	$ –
Certificate of Deposit	325	325	–	–
Total Assets	$ 86,608	$ 86,608	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 5,425	$ –	$ –	$ 5,425

The table below summarizes the activity of Level 3 inputs measured on a recurring basis for the six months ended June 30, 2014 and 2013:

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2013	$ 5,425
Exercise of warrants	(375)
Change in fair value of common stock warrant liability	(1,826)
Balance at June 30, 2014	$ 3,224

(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	(2,686)
Balance at June 30, 2013	$ 3,619

The significant unobservable inputs used in the fair value measurement of the common stock warrants measured on a recurring basis 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, certain fair value measurements also take 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, may result in significantly higher or lower fair value measurements.

Significant Unobservable Input Assumptions of Level 3 Valuations	June 30, 2014	December 31, 2013
Historical Volatility	52% – 61%	62% – 76%
Expected Term (in years)	0.7 – 1.6	0.4 – 2.1
Risk-free interest rate	0.08% – 0.34%	0.08% – 0.44%

Fair Value of Long-Term Debt

At June 30, 2014, the estimated fair value of the Deerfield Loan was $23.2 million compared to a carrying value, net of discounts, of $19.3 million. At December 31, 2013, the estimated fair value of the Deerfield Loan was $23.6 million compared to a carrying value, net of discounts, of $18.4 million. The estimated fair value of the Deerfield Loan was based on discounting the future contractual cash flows to the present value. This analysis utilizes certain Level 3 unobservable inputs, including current cost of capital. Considerable judgment is required to interpret market data and to develop estimates of fair value. The estimates presented are not necessarily indicative of amounts that could be realized in a current market exchange. The use of alternative market assumptions and estimation methodologies could have a material effect on these estimates of fair value.

Note 5 – Inventory

Inventory is comprised of the following for the periods presented:

(in thousands)	June 30, 2014	December 31, 2013
Inventories, current:		
Raw materials	$ 147	$ 52
Finished goods, net of reserves	296	60
	443	112
Inventories, non-current:		
Raw materials	400	–
Total inventories, net	$ 843	$ 112

Raw materials inventory that is not expected to be used in commercial production until more than 12 months from the balance sheet date is classified as a non-current other asset on the balance sheet. The shelf life of our raw materials is 2-5 years.

In addition, as of June 30, 2014, we had $0.7 million of raw materials that were purchased prior to October 4, 2013, the date the FDA approved updated SURFAXIN product specifications, which enabled the commercial introduction of SURFAXIN. These raw materials have a carrying value of zero, as the costs to purchase this material were expensed in the period of purchase as research and development expense, and accordingly are not reflected in the inventory balances shown above. These raw materials are anticipated to be used in manufacturing development, research and development activities and in the manufacture of commercial product.

Inventory reserves as of June 30, 2014 and December 31, 2013 were $2.0 million and $0.5 million, respectively. Inventory reserves reflect costs of SURFAXIN finished goods inventories that are not anticipated to be recoverable through the commercial sale of the product during the initial launch period due to product expiration. These reserves ensure that the inventory carrying values do not exceed net realizable value.

Note 6 – Common Stock Warrant Liability

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

The form of warrant agreement for the registered warrants that we issued in our February 2010 public offering generally provide that, in the event a related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. Notwithstanding the availability of cashless exercise, under GAAP, these registered warrants are deemed to be subject to potential net cash settlement and must be classified as derivative liabilities because (i) under federal securities laws, issuing freely-tradable registered shares upon exercise of the warrants may not be within our control in all circumstances, and (ii) the warrant agreements do not expressly provide that there is no circumstance in which we may be required to effect a net cash settlement of the warrants. The accounting guidance expressly precludes an evaluation of the likelihood that cash settlement could occur. Accordingly, the February 2010 warrants have been classified as a derivative liability and reported, at each balance sheet date, at estimated fair value determined using the Black-Scholes option-pricing model.

The form of warrant agreement for the registered warrants that we issued in the February 2011 public offering (February 2011 warrants) contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the February 2011 warrants. Although by their express terms, these warrants are not subject to potential cash settlement, due to the nature of the anti-dilution provisions, these warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model.

Selected terms and estimated fair value of warrants accounted for as derivative are as follows:

Issuance Date	Number of Warrant Shares Issuable	Exercise Price	Warrant Expiration Date	Fair Value of Warrants (in thousands) Value at Issuance Date	June 30, 2014	December 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	–	6
2/22/2011	4,552,600	1.50	2/22/2016	8,004	3,224	5,419
					$ 3,224	$ 5,425

There were no warrants exercised during the three months ended June 30, 2014. During the six months ended June 30, 2014, holders of the February 2011 warrants exercised warrants to purchase 282,350 shares of common stock for total proceeds of $0.4 million. There were no warrants exercised during the three and six months ended June 30, 2013.

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

Note 7 – Deerfield Loan

Long-term debt consists solely of amounts due under a $30 million loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for the periods presented:

(in thousands)	June 30, 2014	December 31, 2013
Note Payable	$ 30,000	$ 30,000
Unamortized discount	(10,736)	(11,646)
Long-term debt, net of discount	$ 19,264	$ 18,354

The principal amount of the loan is payable in three equal annual installments on the fourth, fifth and sixth anniversaries of the Deerfield Loan agreement beginning in February 2017, provided that the amount payable on the fourth anniversary shall be deferred for one year if either (i) “Net Sales” for the immediately preceding 12-month period are at least $20 million, or (ii) “Equity Value” 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 (i) “Net Sales” for the immediately preceding 12-month period are at least $30 million, or (ii) “Equity Value” is at least $250 million. 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, February 13, 2019.

The following amounts comprise the Deerfield Loan interest expense for the periods presented:

(in thousands)	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
Cash interest expense	$ 654	$ 218	$ 1,302	$ 331
Non-cash amortization of debt discounts	470	118	909	177
Amortization of debt costs	5	5	10	8
Total interest expense	$ 1,129	$ 341	$ 2,221	$ 516

Cash interest expense represents interest at an annual rate of 8.75% on the outstanding principal amount for the period, payable quarterly in cash. Non-cash amortization of debt discount represents the amortization of transaction fees and the fair value of the warrants issued in connection with the Deerfield Loan. The amortization of debt costs represents legal costs incurred in connection with the Deerfield Loan.

In connection with the loan, we issued to Deerfield warrants to purchase 7.0 million shares of our common stock at an exercise price of $2.81 per share that expire on February 13, 2019. The Deerfield warrants are derivatives that qualify for an exemption from liability accounting provided in ASC 815 and are classified as equity. *See*, Note 9, "Deerfield Loan," to the consolidated financial statements in our 2013 Form 10-K.

Note 8 – Stock Options and Stock-Based Employee Compensation

We recognize in our consolidated 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 based on the following weighted average assumptions:

	June 30, 2014	June 30, 2013
Weighted average expected volatility	100%	110%
Weighted average expected term	5.4 years	4.7 years
Weighted average risk-free interest rate	1.6%	0.74%
Expected dividends	–	–

The table below summarizes the total stock-based compensation expense included in the statements of operations for the periods presented:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Research & Development	$ 299	$ 200	$ 547	$ 341
Selling, General & Administrative	482	407	938	622
Total	$ 781	$ 607	$ 1,485	$ 963

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, 2013 that we filed with the Securities and Exchange Commission (SEC) on March 17, 2014 (2013 Form 10-K) and our other filings with the SEC, and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.

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

OVERVIEW

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on creating life-saving products for critical-care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug technology produces a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies and devices potentially to enable efficient delivery of our aerosolized KL_4 surfactant. We believe that our proprietary technologies may 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.

We are initially focused on improving 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. RDS is the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU) and can result in long-term respiratory problems, developmental delay and death. Our first KL_4 surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL_4 surfactant in liquid form, and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States (U.S.). SURFAXIN has been commercially available in the U.S. since November 2013.

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may result in serious respiratory conditions and other complications. To avoid such complications, many neonatologists initially treat infants with less severe RDS by less invasive means, typically nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of premature infants on nCPAP will not respond well (an outcome referred to as nCPAP failure) and thereafter may require endotracheal intubation, mechanical ventilation, and delayed surfactant therapy. Since neonatologists currently cannot predict which infants will experience nCPAP failure, neonatologists are faced with difficult choices in treating infants with less severe RDS. This is because the medical outcomes for those infants who experience nCPAP failure and receive delayed surfactant therapy may be less favorable than the outcomes for infants who receive surfactant therapy in the first hours of life.

AEROSURF® is our investigational combination drug/device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). AEROSURF potentially will enable administration of aerosolized KL_4 surfactant to premature infants supported with nCPAP, without invasive intubation and mechanical ventilation. By enabling delivery of our KL_4 surfactant using less invasive procedures, we believe that AEROSURF may address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

We are also developing a lyophilized (freeze-dried) dosage form of our KL_4 surfactant that is stored as a powder and reconstituted 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 initially developing this dosage form for use in our AEROSURF development program. We are also planning to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of our KL_4 surfactant under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the U.S. and potentially in other markets.

To support the commercial introduction of SURFAXIN in the U.S. and our other KL_4 surfactant pipeline products, if approved, we have our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL_4 surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL_4 surfactant. In addition, we recognize that our commercial and medical affairs team could potentially support introductions of other synergistic pipeline products, including products owned or developed by third parties for the NICU/PICU. To that end, we would consider potential transactions focused on securing commercial rights to such synergistic products, including in the form of product acquisitions, in-licensing agreements or distribution, marketing or co-marketing arrangements.

In the future, we expect that we may be able to leverage the information, data and know-how that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a product pipeline to address serious critical care respiratory conditions in larger children and adults in pediatric and adult intensive care units (PICUs and ICUs), including potentially acute lung injury (ALI), chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). At the present time, however, we are focusing our resources primarily on the commercial introduction of SURFAXIN and development of AEROSURF through phase 2 clinical trials. Once we have advanced these objectives, we expect to be in a better position to assess the potential of other development programs to address the critical care needs of patients in the PICU and ICU.

Business and Pipeline Programs Update

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business," in our 2013 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 KL4 pipeline programs.

Following are updates to our pipeline programs since the filing of our 2013 Form 10-K:

- SURFAXIN is the first synthetic, peptide-containing alternative to the previously available animal-derived surfactants. We initiated the commercial introduction of SURFAXIN in late 2013. Our commercial and medical teams currently are primarily focused on securing formulary acceptance or allowance for restricted use with hospitals that we believe to be recognized centers of excellence with strong reputations and regional and national influence in the neonatal community, as well as affiliated and regional hospitals. We believe that gaining formulary acceptance at selected centers of excellence could enhance our ability to gain formulary acceptance at other regional and national medical centers. We also are focused on providing in-service training to hospitals to assure that SURFAXIN is administered in a safe and consistent manner. Although not an indicator or predictor of revenue, in most cases, formulary acceptance is a necessary prerequisite to be able to sell SURFAXIN drug product to a hospital.

  Our experience to date indicates that the time required to have SURFAXIN reviewed by hospital committees, accepted on hospital formulary, purchased by the hospital pharmacy, and ultimately used in the NICU is longer than we had expected. As a result, while we continue to believe that we will achieve wide market acceptance for SURFAXIN, we anticipate that revenues from sales of SURFAXIN will be modest in the next several years. Our experience also suggests that, to better inform the formulary committee review process and properly explain the method of administration and the potential benefits of SURFAXIN, including both potential medical and pharmacoeconomic benefits, it is important to emphasize medical education and scientific discussions. Therefore, in the second quarter of 2014, we resized and realigned our commercial and medical affairs teams to emphasize medical education balanced with an appropriate sales effort. We expect that this realignment could result in a reduction in expense in the second half of 2014 of approximately $1.0 million per quarter compared to recent historical expense

  As we continue to monitor and learn from our progress, we plan to routinely reassess and adjust our tactical plan and make appropriate additional investments, if needed, to increase formulary uptake and SURFAXIN sales revenue. There can be no assurance, however, that we will succeed in these efforts.

- Our AEROSURF phase 2 clinical program is underway. This initial phase 2a clinical trial was designed to assess the safety and tolerability of aerosolized KL4 surfactant in premature infants 29 to 32 weeks gestational age receiving nCPAP for RDS. In the second quarter of 2014, we experienced slower early enrollment than anticipated. During this time, we conducted an analysis of potentially eligible patient populations at our clinical trial sites and noted that a sizeable number of premature infants 33 to 34 weeks gestational age would potentially meet study eligibility requirements and may benefit from aerosolized KL4 surfactant. After consulting our clinical sites, AEROSURF Clinical Trial (ACT) Steering Committee, and Safety Review Committee (SRC), we have implemented trial protocol changes increasing the gestational age range to 29 to 34 weeks and expanding the number of patients in the trial to 42 from 36. As a result of the early slow enrollment and expansion of the number of patients, we now expect that the results of this trial will be available in the fourth quarter of 2014. We also are initiating activities to prepare for a phase 2b clinical trial, with results expected in the second half of 2015.

- We continue to focus on implementing a long-term manufacturing strategy to assure continuity of our KL4 surfactant drug supply and are pursuing several alternatives.

  - We are working to identify potential alternatives that would enable longer-term utilization of our manufacturing facility in Totowa, NJ (Totowa Facility), the lease for which currently is scheduled to expire on June 30, 2015. At the present time, our Totowa Facility is the only approved manufacturing facility for SURFAXIN commercial product. We are actively engaged in discussions with the landlord, which is pursuing strategic options for the entire facility. We are also pursuing potentially manufacturing SURFAXIN using third-party CMOs. At this time, however, it is unlikely that we could complete the technology transfer of our SURFAXIN liquid KL4 surfactant manufacturing process in time to secure FDA approval for a new manufacturer of SURFAXIN prior to the scheduled expiration date of our lease. Accordingly, our primary goal currently is to secure longer-term utilization of our Totowa Facility. We believe that we will be successful in achieving our goal; however, if we do not succeed, we most likely will experience an interruption in supply of SURFAXIN drug product. *See*, Item 1A "–Risk Factors."

- With respect to our lyophilized KL4 surfactant, we have worked with Patheon Inc. (Patheon, formerly DSM Pharmaceuticals, Inc.) to complete a technology transfer of our lyophilized KL4 surfactant manufacturing process and complete early manufacturing development activities. Patheon successfully manufactured a sufficient supply of lyophilized KL4 surfactant drug product to support our preclinical activities, development activities for our clinic-ready CAG, as well as our ongoing phase 2a clinical trial. We are working with Patheon to manufacture additional clinical supply to support our phase 2b clinical trial and have entered into a development agreement for the potential further development and manufacture of lyophilized KL4 surfactant for our potential AEROSURF phase 3 clinical program, as well as other potential pipeline development programs.

- In the second quarter 2014, we secured three additional patents in the U.S., including two patents containing composition of matter and method of making claims for our lyophilized KL4 surfactant, which extend to 2033, and one related to our novel AFECTAIR® aerosol-conducting airway connector for infants that extends to April 2029. This device is intended to simplify the delivery of aerosolized medications and other inhaled therapies to critical-care infants requiring ventilatory support. We believe that these patents are indicative of our efforts to protect the long-term commercial potential of our KL4 surfactant and aerosol delivery technologies. Our lyophilized KL4 surfactant is being developed initially for our AEROSURF development program. Our longer term goal is to develop our technologies to address other potential indications that could benefit from our proprietary KL4 surfactant.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2013. For a discussion of our accounting policies, *see*, Note 3, "Accounting Policies and Recent Accounting Pronouncements," to the consolidated financial statements in our 2013 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Recent accounting pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. generally accepted accounting principles (GAAP) when it becomes effective. The new standard is effective for us in our fiscal year 2017. Early application is not permitted. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the three months ended June 30, 2014 and 2013 was $10.6 million (or $0.12 basic net loss per share) and $8.6 million (or $0.18 basic net loss per share), respectively. Included in the net loss is (i) the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $1.4 million and $2.5 million for 2014 and 2013, respectively, and (ii) interest expense of $1.1 million and $0.3 million for 2014 and 2013, respectively, associated with the Deerfield Loan.

The net loss for the six months ended June 30, 2014 and 2013 was $22.1 million (or $0.26 basic net loss per share) and $21.3 million (or $0.46 basic net loss per share), respectively. Included in the net loss is (i) the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $1.8 million and $2.7 million for 2014 and 2013, respectively, and (ii) interest expense of $2.2 million and $0.5 million for 2014 and 2013, respectively, associated with the Deerfield Loan.

The operating loss for the three months ended June 30, 2014 and 2013 was $10.9 million and $10.8 million, respectively. The increase in operating loss from 2013 to 2014 was due to a $1.0 million increase in operating expenses, partially offset by a $0.9 million increase in grant revenues.

The operating loss for the six months ended June 30, 2014 and 2013 was $21.7 million and $23.4 million, respectively. The decrease in operating loss from 2013 to 2014 was due to a $0.9 million decrease in operating expenses and a $0.8 million increase in grant revenues.

Product Sales

In accordance with our revenue recognition policy, we recognize revenue once product has been sold through to the hospital and all revenue recognition criteria have been met. For the three and six months ended June 30, 2014, we recognized revenue in the amount of $42,000 and $70,000, respectively.

Grant Revenue

We recognized grant revenue of $1.1 million for both the three and six months ended June 30, 2014. During the second quarter of 2014, we were awarded the final $1.9 million of a $2.4 million Fast Track Small Business Innovation Research (SBIR) Grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). This award provides support for the ongoing phase 2a clinical trial for AEROSURF. Our eligibility to be considered under this grant program was originally confirmed in 2010, and we previously received $0.6 million to support development activities related to our capillary aerosol generator technology. We expect to utilize the entire $1.9 million during 2014.

For the three and six months ended June 30, 2013, we recognized grant revenue of $0.2 million and $0.3 million, respectively. The grant funds were received and expended under a $0.6 million SBIR Phase I award from NIH's 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.

Cost of product sales

Cost of product sales for the three and six months ended June 30, 2014 was $0.7 million and $1.5 million, respectively, and represents reserves for SURFAXIN finished goods inventories that are not anticipated to be recoverable through the commercial sale of the product during the initial launch period due to product expiration.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and are tracked by category rather than by development project. As many of our research and development activities form a foundation for the development of our KL4 surfactant and drug delivery technologies, they are expected to 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 of expenses associated with (a) product development and manufacturing, (b) medical and regulatory operations, (c) direct preclinical and clinical programs, and (d) other related expenses.

The table below summarizes research and development expenses for the periods presented:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Product development and manufacturing	$ 3,298	$ 4,998	$ 6,922	$ 11,822
Medical and regulatory operations	2,214	1,459	3,847	2,910
Direct preclinical and clinical programs	1,346	406	1,679	603
Total Research & Development Expenses	$ 6,858	$ 6,863	$ 12,448	$ 15,335

Research and development expenses for the three months ended June 30, 2014 and 2013 include non-cash charges associated with stock-based compensation and depreciation of $0.5 million and $0.4 million, respectively; and $0.9 million and $0.7 million for the six months ended June 30, 2014 and 2013, respectively.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with CMOs, validation activities and quality assurance and analytical chemistry capabilities to support production of drug supply for our KL4 surfactant products used in research and development activities, and of medical devices, including CAG and AFECTAIR devices, (ii) design and development activities related to our CAG device for use in our AEROSURF phase 2 clinical program; and (iii) pharmaceutical and manufacturing 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 for the three months ended June 30, 2014 decreased $1.7 million compared to the same period in 2013, due to (i) investments of $1.4 million in 2013 to complete development activities for our clinic-ready CAG device for use in our AEROSURF phase 2 clinical trials, including work that began in June 2012 with Battelle Memorial Institute (Battelle), which assisted with the device design and testing, and manufactured a supply of clinic-ready CAG devices for use in the initial AEROSURF phase 2a clinical trial, and (ii) $1.1 million of costs capitalized to SURFAXIN inventory in 2014, partially offset by (iii) a $0.2 million increase in purchases of active pharmaceutical ingredients (APIs) used in the manufacture of SURFAXIN and our lyophilized KL4 surfactant for the AEROSURF development program .

Product development and manufacturing expenses for the six months ended June 30, 2014 decreased $4.9 million compared to the same period in 2013, due to (i) investments in 2013 of $2.6 million to complete development activities for our clinic-ready CAG device for use in our AEROSURF phase 2 clinical trials, (ii) $2.0 million of costs capitalized to SURFAXIN inventory in 2014, and (iii) a reduction of $1.0 million in purchases of APIs used in the manufacture of SURFAXIN commercial drug product and our lyophilized KL4 surfactant for use in preclinical and clinical development activities, including the technology transfer of our KL4 surfactant manufacturing process to Patheon, further drug development at Patheon, and activities to prepare for our AEROSURF phase 2 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 SURFAXIN, 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 expenses for the three months ended June 30, 2014 increased $0.8 million compared to the same period in 2013 due to (i) a $0.4 million increase related to our medical affairs capabilities to support the commercial introduction of SURFAXIN, and (ii) a $0.2 million increase to strengthen our clinical leadership team and support our AEROSURF development program.

Medical and regulatory operations expenses for the six months ended June 30, 2014 increased $0.9 million compared to the same period in 2013 due to (i) a $0.4 million increase related to our medical and regulatory capabilities to support our AEROSURF development program, including to strengthen our clinical leadership team, and (ii) a $0.3 million increase related to our medical affairs capabilities to execute the commercial introduction of SURFAXIN.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) development activities, toxicology studies and other preclinical studies to obtain data to support our investigational new drug (IND) applications and, potentially, New Drug Application (NDA) filings; and (ii) activities associated with conducting clinical trials, including patient enrollment costs, external site costs, clinical device and drug supply, and related external costs, such as research consultant fees and expenses.

Direct preclinical and clinical programs expenses for the three months ended June 30, 2014 increased $0.9 million compared to the same period in 2013 due to (i) a $0.7 million increase in AEROSURF clinical trial activities, including ongoing enrollment of the Phase 2a study and initiating the manufacture of clinic-ready CAG devices for the AEROSURF Phase 2b clinical study, and (ii) $0.4 million of preclinical activities in 2014 related to our lyophilized dosage form of our KL_4 surfactant.

Direct preclinical and clinical programs expenses for the six months ended June 30, 2014 increased $1.1 million compared to the same period in 2013 due to (i) a $0.8 million increase in AEROSURF clinical trial activities, including ongoing enrollment of the Phase 2a study and initial manufacturing of clinic-ready CAG devices for the planned AEROSURF Phase 2b clinical study, and (ii) $0.5 million of preclinical activities in 2014 related to our lyophilized dosage form of our KL_4 surfactant.

We anticipate that direct clinical program costs associated with conducting the AEROSURF phase 2 clinical program will be approximately $10 - 11 million for 2014 and through the anticipated completion of the AEROSURF phase 2 program as expected in 2015.

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. In view 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 “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” in our 2013 Form 10-K.

Our research and development projects have been focused initially on the management of RDS in premature infants, and include (i) SURFAXIN liquid instillate, which was approved by the FDA in 2012 and introduced commercially in 2013, (ii) our lyophilized KL_4 surfactant, which we are developing initially for use in our AEROSURF development program and, if we are able to gain FDA agreement for a development program that would be both capital efficient and capable of implementation within a reasonable time, potentially, SURFAXIN LS; (iii) our aerosol delivery technology, in particular the development of a CAG device to support our AEROSURF phase 2 clinical program; and (iv) AEROSURF phase 2 clinical trial activities. These and our other development programs are described “Item 1 – Business – Proprietary Platform – Surfactant and Aerosol Technologies,” and “- Surfactant Replacement Therapy for Respiratory Medicine” in our 2013 Form 10-K, and in our other periodic filings with the SEC.

To prepare for initiation of the AEROSURF phase 2 clinical program, during 2012 through 2013, we invested approximately $7 million to develop a clinic-ready CAG device with Battelle and our lyophilized KL4 surfactant manufacturing process at Patheon. We anticipate that direct clinical program costs associated with conducting the AEROSURF phase 2 clinical program will be approximately $10 - 11 million for 2014 and through the completion of phase 2b as expected in 2015. We also plan to invest in appropriate capabilities to support the further advancement of AEROSURF, including for manufacturing development of our lyophilized KL4 surfactant, the conduct of a phase 3 clinical program, and further development of a CAG device suitable for use in a phase 3 clinical program and, if successful, commercial use.

At the present time, we are focusing our efforts primarily on the commercial introduction of SURFAXIN and development of AEROSURF through the phase 2 clinical trials. We also believe that, in the future, we may be able to leverage the information, data and know-how that we gain from our work with SURFAXIN and AEROSURF to support development of a robust product pipeline that could address serious critical care respiratory conditions in larger children and adults in PICUs and ICUs, including potentially ALI, COPD and CF.

The reader is referred to and encouraged to review updates to the Pipeline Programs in “– Overview,” and “–Business and Pipeline Programs Update” at the beginning of this MD&A, which contain important updates and information necessary and important to this discussion. *See also*, “– Liquidity and Capital Resources.”

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Selling, General and Administrative Expenses	$ 4,446	$ 4,129	$ 8,869	$ 8,349

Selling, general and administrative expenses consist of the costs of sales and marketing activities, executive management, business development, intellectual property, finance and accounting, legal, human resources, information technology, facilities and other administrative costs.

Selling, general and administrative expenses for the three and six months ended June 30, 2014 increased $0.3 million and $0.5 million, respectively, compared to the same periods in 2013 due to (i) increased investments in our marketing and field-based sales force to execute the commercial introduction of SURFAXIN, and (ii) an increase in related stock-based compensation expense.

Change in Fair Value of Common Stock Warrant Liability

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Change in fair value of common stock warrant liability	$ 1,448	$ 2,525	$ 1,826	$ 2,686

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC Topic 815 *"Derivatives and Hedging – Contracts in Entity's Own Equity"* (ASC 815), either as 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*, Note 6 to our consolidated financial statements in this Quarterly Report on Form 10-Q, and "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Change in Fair Value of Common Stock Warrant Liability" our 2013 Form 10-K.

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

Other Income and (Expense)

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Interest income	$ 2	$ 1	$ 4	$ 1
Interest expense	(1,131)	(343)	(2,224)	(520)
Other income / (expense), net	$ (1,129)	$ (342)	$ (2,220)	$ (519)

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 consists of interest expense associated with the Deerfield Loan (*see*, Note 7 to our consolidated financial statements in this Quarterly Report on Form 10-Q) and interest expense incurred under our equipment financing facilities.

The following amounts comprise the Deerfield Loan interest expense for the periods presented:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Cash interest expense	$ 654	$ 218	$ 1,302	$ 331
Non-cash amortization of debt discounts	470	118	909	177
Amortization of debt costs	5	5	10	8
Total interest expense	$ 1,129	$ 341	$ 2,221	$ 516

Cash interest expense represents interest at an annual rate of 8.75% calculated on the outstanding principal amount for the period, paid in cash on a quarterly basis. Non-cash amortization of debt discount represents the amortization of transaction fees and the fair value of the Deerfield Warrants. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, and, more recently, commercialization and medical affairs 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, debt facilities, strategic alliances, the use of committed equity financing facilities (CEFFs) and at-the-market (ATM) equity programs, and capital equipment financings.

As of June 30, 2014, we had cash and cash equivalents of $65.6 million and long-term debt of $30 million ($19.3 million net of discount) under our Deerfield Loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 7, “Deerfield Loan,” to our consolidated financial statements in this Quarterly Report on Form 10-Q). Before any additional financings, including under our ATM Program (see, “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – At-the-Market Program (ATM Program) – Stifel ATM Program,” in our 2013 Form 10-K), we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the third quarter of 2015.

For the next several years, we expect that our cash outflows for marketing, commercial and medical activities, development programs, operations and debt service will outpace the rate at which we may generate revenues. To execute our business strategy, pay debt obligations and fund our operations over the next several years, we will require significant additional infusions of capital until such time as the net revenues from the sale of approved products and from other sources are sufficient to offset our cash flow requirements. While we currently intend to retain all rights and commercialize our approved products in the U.S. by ourselves, an important priority for us is to identify strategic transactions that could provide additional capital and strategic resources to support the continued development and commercial introduction of our RDS products in markets outside the U.S. For our AEROSURF development program, we seek a significant strategic alliance that potentially could provide development, regulatory and commercial market expertise, and, if approved, support the commercial introduction of AEROSURF in the EU and other selected markets outside the U.S. Such alliances typically also would provide financial resources, in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. To advance SURFAXIN in markets outside the U.S. where regulatory marketing authorization is facilitated by the information contained in our new drug application (NDA) approved by the FDA, we would consider various financing or collaboration arrangements that could provide regulatory expertise, support the commercial introduction of SURFAXIN in markets outside the U.S., and potentially provide a sharing of revenues. Such countries could potentially include those in Latin America, North Africa and the Middle East. To secure the necessary capital, we also plan to consider other public and private equity offerings, including under our ATM Program, which currently may allow for the sale of up to approximately $23 million of our commons stock, as well as other financing transactions, such as secured equipment financing facilities or other similar transactions.

Our future capital requirements will depend upon many factors, primarily our efforts to (i) execute the commercial introduction of SURFAXIN in the U.S.; (ii) advance the AEROSURF development program to completion of the phase 2 clinical trials as planned in the second half of 2015; (iii) assure long-term continuity of supply for both our commercial and lyophilized KL_4 surfactant drug product, potentially with CMOs and/or at Totowa Facility; and (iv) secure one or more strategic alliances or other collaboration arrangements to support our development programs and commercialization of our approved products, if any, in markets outside the U.S. We believe that we will be better positioned to enter into a significant strategic alliance if we are successful in advancing the commercial introduction of SURFAXIN and completing and obtaining encouraging results from the AEROSURF phase 2 clinical program within our anticipated time.

Although we currently believe that we will be able to successfully execute our business strategy as planned, there can be no assurance that any of our approved products, including SURFAXIN, will be commercially viable or that we will be able to execute our long-term manufacturing plan, that our AEROSURF development program will be successful within our anticipated time frame, if at all, that we will be able to secure regulatory marketing authorization for AEROSURF and our other KL4 surfactant product candidates, in the U.S. and other markets, that the ATM Program will be available when needed, if at all, or that we will be able to obtain additional capital when needed and on acceptable terms. We will require significant additional capital to sustain operations, satisfy debt obligations, and complete product development and execute the commercial introduction of our KL4 surfactant product candidates, if approved. Failure to secure the necessary additional capital when needed would have a material adverse effect on our business, financial condition and results of operations. Even if we succeed in raising additional capital and developing and subsequently commercializing our product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of June 30, 2014, we had outstanding warrants to purchase approximately 14.0 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, warrants to purchase 7 million shares were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share. The Deerfield Warrants may be exercised for cash or on a cashless basis. In lieu of paying cash upon exercise, the holders also may elect to reduce the principal amount of the Deerfield Loan in an amount sufficient to satisfy the exercise price of the Deerfield Warrants. In addition to the Deerfield Warrants, we have outstanding warrants issued in February 2011 to purchase approximately 4.6 million shares of common stock that 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 currently have an exercise price of $1.50 per share and expire in February 2016. Although we believe that, in the future, we may receive 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 would make exercise of outstanding warrants likely, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. 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.

As of June 30, 2014, 250 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation and approximately 137.2 million shares of common stock were available for issuance and not otherwise reserved.

Cash Flows

As of June 30, 2014, we had cash and cash equivalents of $65.6 million compared to $86.3 million as of December 31, 2013. Cash outflows before financing activities for the six months ended June 30, 2014 consisted of $20.3 million used for ongoing operating activities and $0.9 million for purchases of property and equipment. Cash provided by financing activities were $0.4 million of proceeds from the exercise of warrants and stock options.

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2014 and 2013 was $20.3 million and $20.4 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2014 and 2013 represents capital expenditures of $0.9 million and $0.1 million, respectively. The increase in capital expenditures is due to timing of routine equipment purchases.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2014 and 2013 was $0.4 million and $24.9 million, respectively. Net cash provided by financing activities for the six months ended June 30, 2014 represents proceeds from the exercise of warrants and stock options. Net cash provided by financing activities for the six months ended June 30, 2013 includes proceeds of $15.1 million pursuant to a common stock offering and the first advance in February 2013 of $10.0 million ($9.9 million, net) under the Deerfield Loan.

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 May 2014, we filed with the SEC a universal shelf registration statement on Form S-3 (No. 333-196420) (2014 Universal Shelf) that was declared effective on June 13, 2014 for the proposed offering from time to time of up to $250 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 the time of an offering. The 2014 Universal Shelf replaces an expired 2011 Universal Shelf. As of June 30, 2014, after reserves for outstanding unexercised warrants and amounts remaining under our ATM Program, approximately $199.0 million remained available under the 2014 Universal Shelf. The 2014 Universal Shelf will expire in June 2017.

At-the-Market Program (ATM Program)

We have an ATM Program with Stifel, Nicolaus & Company, Incorporated (Stifel), under 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 ending February 11, 2016. We are not required to sell any shares at any time during the term of the ATM Program. We have agreed to pay Stifel a commission of 3% of gross proceeds of any sales of shares. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – At-the-Market Program (ATM Program) – Stifel ATM Program," in our 2013 Form 10-K. As of June 30, 2014, approximately $23 million shares of common stock remained available under the ATM Program.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Our management, including our President and Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal financial officer), does not expect that our disclosure controls 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 our Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer and our Chief Financial Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in internal controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended June 30, 2014 that has materially affected, or is 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 2013 Form 10-K, as supplemented by the risks and uncertainties discussed below and elsewhere in this Quarterly Report on 10-Q. The risks and uncertainties discussed in this Quarterly Report on Form 10-Q and described in our 2013 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 to be immaterial may also impair our business operations. If any of the risks and uncertainties discussed in this Quarterly Report on Form 10-Q or in our 2013 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 projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions we make in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of projections in this Form 10-Q or in our periodic reports and current reports on Form 8-K should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

Our efforts to achieve formulary acceptance of SURFAXIN, and to educate the medical community and third-party payers regarding the benefits of SURFAXIN, will require significant, focused and competent resources and we may not be successful in achieving our objectives. If we are unable to achieve formulary acceptance in our target hospitals, the revenues we generate from sales likely will be limited, which could have a material adverse effect on our operations, and our commercial and development programs.

We initiated the commercial introduction of SURFAXIN in late 2013. SURFAXIN product sales are expected to constitute most, if not all, of our total revenue from product sales over the next several years. If we fail to successfully commercialize SURFAXIN for any reason, we will be exposed to the following risks, among others:

- Our ability to achieve broad market acceptance of our other KL4 surfactant products by physicians, respiratory therapists, nurses and other personnel in the NICU and elsewhere in the hospital, as well as patients, healthcare payers and others in the medical community in general, may be negatively impacted, which could impair our ability to develop, and if approved, commercialize other KL4 surfactant products

- The market price of our stock could be adversely affected, which may make it more difficult to conduct equity financing transactions, attract strategic partners or enter into collaboration or other agreements and maintain compliance with the listing requirements of The Nasdaq Capital Market.

- We may be unable to pay our debt service. We have pledged substantially all of our assets to secure our obligations under a $30 million loan (Deerfield Loan) from affiliates of Deerfield Management Company, L.P. (Deerfield). If we were to fail in the future to make any required payment under the Deerfield Loan or fail to comply with the covenants contained in the facility agreement and other related agreements, we would be in default regarding that indebtedness, which would enable the lenders to foreclose on the assets securing such debt and could result in the acceleration of the payment obligations under all or a portion of our consolidated indebtedness.

Our long-term manufacturing strategy includes potentially manufacturing our KL4 surfactant at our Totowa Facility, and relying on third parties to manufacture our approved products as well as our drug product and medical device candidates, all of which expose us to risks that may affect our ability to maintain supplies of our commercial products and/or delay our research and development activities, regulatory approval and commercialization of our drug product and medical device candidates.

We currently manufacture SURFAXIN at our manufacturing operations in Totowa, New Jersey (Totowa Facility), for which our lease is currently scheduled to expire in June 2015. We also expect to manufacture lyophilized KL4 surfactant, our CAG, WARMING CRADLE® and AFECTAIR® devices, with CMOs. Our manufacturing plans could expose us to the following risks:

- We are currently in discussions with our landlord to potentially secure long-term utilization of that facility. We believe that our efforts will be successful; however, if we are unable to succeed, we most likely will experience an interruption in supply of SURFAXIN drug product.

- In seeking to identify CMOs to manufacture products on our behalf, we may be unable to identify manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all, because the number of potential CMOs is limited and the FDA must approve any replacement CMO. This approval could require one or more pre-approval inspections as well as a potentially lengthy qualification process. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our approved products after receipt of FDA approval. This could take as long as 2 years to qualify and receive regulatory approval.

- We may implement a plan to execute a technology transfer of our manufacturing process to a CMO and, after investing significant time and resources, learn that the CMO we chose is unable to successfully complete the technology transfer and manufacture our products in accordance with our plan.

- CMOs might be unable to manufacture our products in the volume and to our specifications to meet our commercial, preclinical and clinical needs, or we may have difficulty scheduling the production of drug product and devices in a timely manner to meet our timing requirements.

- CMOs may not perform as agreed, or may not remain in the CMO business for a lengthy time, or may refuse to renew an expiring agreement as expected, or may fail to produce a sufficient supply to meet our commercial and/or clinical needs.

- CMOs are subject to ongoing periodic unannounced inspection by the FDA, international health authorities, registered Notified Bodies, the U. S. Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with current good manufacturing practices (cGMP) and/or quality system regulations (QSR) and other government regulations and corresponding foreign standards. We do not have control over a CMO’s compliance with these regulations and standards.

- Should we desire to make our drug products and/or devices available outside the U.S. for commercial or clinical purposes, our CMOs would become subject to, and may not be able to comply with, corresponding cGMPs and QSRs of the various foreign regulators having jurisdiction over our activities abroad. Such failures could restrict our ability to execute our business strategies.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not have rights to, or may have to share, the intellectual property rights to any such innovation. We may be required to pay fees or other costs for access to such improvements.

Each of the foregoing risks and others could create uncertainty concerning our ability to maintain continuous supply of our products and product candidates, delay our commercial manufacturing plans and our development programs, as well as the approval, if any, of our product candidates, by the FDA or foreign regulator, or result in higher costs or deprive us of potential product revenues. Failure to succeed in our efforts could result in interruptions in our manufacturing capabilities and result in potential shortages of drug product.

Our clinical development program for AEROSURF involves significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes. Our clinical trials may be delayed, or fail, which would harm our business prospects.

Our ongoing AEROSURF phase 2a clinical trial is the first of a series of clinical trials that will be needed to gain marketing authorization for AEROSURF. We could experience delays that could have a significant impact on our time line for completion of such trials. Generally, such programs take two to five years or more to complete and may be delayed by a number of factors. We may not reach agreement with the U.S. Food and Drug Administration (FDA) or a foreign regulator on the design of any one or more of the clinical trials necessary for approval, or we may be unable to reach agreement on a single design that would permit us to conduct a single clinical program in multiple jurisdictions. Conditions imposed by the FDA and foreign regulators on our clinical program could significantly increase the time required to complete and the costs of conducting clinical trials. For example, we may not be successful in achieving a study design that is acceptable to both the FDA and regulators in other countries, which would cause us to limit the scope of our activities or greatly increase our investment. Like many biotechnology companies, even after obtaining promising preliminary findings or results in earlier preclinical studies and clinical trials, we may suffer significant setbacks in any stage of our clinical trials. Clinical data is susceptible to varying interpretations that may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials.

The timing and completion of current and planned clinical trials of our product candidates depend on many factors, including the rate at which patients are enrolled. Delays in patient enrollment in clinical trials may occur, which would be likely to result in increased costs, program delays, or both. Patient enrollment is a function of many factors, including:

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

In addition, if in our clinical trials we succeed in achieving our patient enrollment targets, our patients could suffer adverse medical events or side effects that are known to be associated with surfactant administration, such as a decrease in the oxygen level of the blood, or currently unknown to us. It is also possible that we, our AEROSURF Clinical Trial (ACT) Steering Committee, the Safety Review Committee (SRC), or the FDA could interrupt, delay or halt any one or more of our clinical trials for AEROSURF or any of our product candidates. If our ACT Steering Committee, the SRC, any regulator or we believe that study participants face unacceptable health risks, any one or more of our clinical trials could be suspended or terminated. In addition, clinical trials may be interrupted, delayed or halted, in whole or in part, for reasons other than health and safety concerns, including, among other things, matters related to the design of the study, drug availability, ACT Steering Committee and/or SRC recommendation, or business reasons. Even if we timely complete a clinical trial, we may fail to achieve the desired endpoints.

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

We will require, but may be unable to secure when needed, significant additional capital to support our operations, pay our debt service, commercialize our approved products, continue our other research and development programs, and advance our long-term business strategy.

Our operations have consumed substantial amounts of cash since inception. As of June 30, 2014, we had cash and cash equivalents of approximately $66 million and $30 million of long-term debt under a secured loan with affiliates of Deerfield Management Company, L.P. Before any additional financings, including under our ATM Program, we anticipate that we will have sufficient cash available to support our current operations and debt service obligations through the third quarter of 2015.

We expect to continue to require significant additional infusions of capital to be able to execute key components of our long-term business strategy. For example, we expect to make potentially significant additional investments to secure our long-term manufacturing capabilities for our liquid and lyophilized KL_4 surfactant drug product, further the development of our CAG for use in a potential phase 3 clinical program and, if approved, for commercial applications, and to prepare for, initiate and conduct a potential AEROSURF phase 3 clinical program.

If we are unable to secure the additional capital when needed, if at all, on terms that are acceptable, our long-term business strategy would be adversely affected.

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

During the three months ended June 30, 2014, we issued 8,750 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during the three month period ended May 31, 2014. 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: August 7, 2014

By: /s/ John G. Cooper
John G. Cooper
President and Chief Executive Officer

Date: August 7, 2014

By: /s/ John Tattory
John Tattory
Senior Vice President and Chief 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 filed as of August 1, 2013, as amended by a Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery), filed on June 10, 2014	Filed herewith.
3.2	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	Form of Warrant to Purchase Common Stock 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.
4.2	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.
4.3	Warrant Agreement dated June 11, 2010 by and between Kingsbridge Capital Limited and Discovery	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2010.
4.4	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.
4.5	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.
4.6	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.
4.9+	Form of Warrant dated February 13, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) under a Facility Agreement dated as of February 13, 2012 between Discovery and Deerfield	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2013.
4.10+	Form of Warrant dated December 3, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) on December 3, 2013 under a Facility Agreement dated as of February 13, 2012 between Discovery and Deerfield	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 6, 2013.

Exhibit No.	Description	Method of Filing
10.1	Discovery's 2011 Long-Term Incentive Plan	Incorporated by reference to Appendix II to Discovery's Definitive Proxy Statement on Form DEF 14A, as filed with the SEC on August 15, 2011 (Commission File Number 000-26422).
10.2	Amendment to Discovery's 2011 Long-Term Incentive Compensation Plan effective June 10, 2014	Filed herewith
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
31.2	Certification of 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. Annual Report on Form 10-Q for the quarter ended March 31, 2014, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of March 31, 2014 (unaudited) and December 31, 2013, (ii) Statements of Operations (unaudited) for the three months ended March 31, 2014 and March 31, 2013, (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2014 and March 31, 2013, 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 these exhibits. 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 3.1

Amended and Restated Certificate of Incorporation
filed as of August 1, 2013,
as Amended by a Certificate of Amendment to the
Amended and Restated Certificate of Incorporation
of Discovery Laboratories, Inc.,
filed on June 10, 2014

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

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

ARTICLE ONE

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

ARTICLE TWO

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

ARTICLE THREE

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

ARTICLE FOUR

The total number of shares of all classes of stock which the Corporation shall have the authority to issue is 255,000,000 consisting of 250,000,000 shares of common stock, par value $0.001 per share (the "Common Stock"), and 5,000,000 shares of preferred stock, par value $0.001 per share (the "Preferred Stock").

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

ARTICLE FIVE

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

ARTICLE SIX

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

ARTICLE SEVEN

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

ARTICLE EIGHT

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

ARTICLE NINE

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

Exhibit 10.2

AMENDMENT TO THE
DISCOVERY LABORATORIES, INC.
2011 LONG-TERM INCENTIVE COMPENSATION PLAN

The Discovery Laboratories, Inc. 2011 Long-Term Incentive Compensation Plan (the "Plan") is hereby amended as set forth below, effective June 10, 2014:

I.

Section 4(a)(i) of the Plan is hereby amended to read as follows:

"(i) Subject to adjustment as provided in Section 4(b) and to the terms of this Section 4, the total number of Shares reserved and available for delivery pursuant to Awards granted under the Plan shall be (A) twelve million, seven hundred-thousand (12,700,000), plus (B) the number of shares that, immediately prior to the Effective Date, remain available for issuance or delivery under the 2007 Plan; plus (C) the number of shares subject to awards under the 2007 Plan which become available for grant under the Plan in accordance with Section 4(c) after the Effective Date."

II.

Except as set forth herein, the Plan shall remain in full force and effect.

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: August 7, 2014

/s/ John G. Cooper
John G. Cooper
President and Chief Executive

Exhibit 31.2

CERTIFICATIONS

I, John Tattory, 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: August 7, 2014

/s/ John Tattory
John Tattory
Senior Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2014 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.
Date: August 7, 2014

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

/s/ John Tattory
John Tattory
Senior Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to us and will be retained by us and furnished to the SEC or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.