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

FORM 10-Q

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

For the quarterly period ended June 30, 2015
or

☐ **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 ☒ NO ☐

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 ☒ NO ☐

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

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

As of August 1, 2015, there were outstanding 110,999,921 shares of the registrant's common stock, par value $0.001 per share.

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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 provide our current expectations about 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 will enable us to fund our operations. Forward-looking statements also include our financial, clinical, and manufacturing plans, and our expectations related to our development plans and regulatory strategy to secure marketing authorization for our products under development, starting with AEROSURF® for RDS; our research and development programs, planning for development activities, anticipated timing of clinical trials and potential development milestones for our KL4 surfactant pipeline and our capillary aerosol generator (CAG) for delivery of aerosolized medications; our expectations, timing and anticipated outcomes of submitting regulatory filings for our products; our plans for the manufacture and procurement of our KL4 surfactant, active pharmaceutical ingredients (APIs), excipients, materials and medical devices; 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:

- risks related to our efforts to gain regulatory approval in the U.S. and elsewhere for our drug products, medical device and combination drug/device product candidates, including AEROSURF, and our lyophilized KL4 surfactant, which we are developing initially to be the drug component of AEROSURF;

- the risk that our AEROSURF phase 2 clinical program may be interrupted, delayed, or fail, which will harm our business prospects;

- risks relating generally to our research and development activities, which among other things may involve time-consuming and expensive preclinical studies and potentially multiple clinical trials that may be subject to significant delays or regulatory holds or fail;

- 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 in the next several years we will require, and may be unable to secure, significant additional capital (whether from strategic alliances, equity financings or other sources) when needed, if at all, to continue our operations, fund our debt service, and support our development program for AEROSURF for respiratory distress syndrome, as well as potential research and development activities for our other KL4 surfactant product candidates, which ultimately could have a material adverse effect on our business, financial condition and results of operations;

- risks that unfavorable credit and financial markets may adversely affect our ability to fund our activities, through our at-the-market equity sales program (ATM Program) or otherwise through equity financings, and that our ATM Program may be exhausted or expire in February 2016 unutilized, and that, at least until such time as our stockholders approve an amendment to our Amended and Restated Certificate of Incorporation, as amended, that has the effect of increasing our available authorized and unreserved shares of common stock, our ability to fund our operations through additional equity financings will be severely limited;

- the risk that we may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us with the development of our KL4 surfactant products, beginning with AEROSURF, and, if approved, commercialization of AEROSURF in markets outside the U.S.; and potentially support the development and, if approved, commercialization, of our other pipeline products;

- risks that, if holders of our outstanding warrants exercise their warrants, 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; and to the extent that holders exercise their warrants in the same period, including in anticipation of a warrant expiration date, such exercises could be accompanied by increased selling activity in the Nasdaq market, which could cause the market value of our common stock to decline;

- risks relating to the transfer of our manufacturing technology to contract manufacturing organizations (CMOs) and assemblers;

- risks relating to our CMOs' ability to manufacture our KL4 surfactant in lyophilized dosage form, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests;

- risks relating to our, Battelle Memorial Institute's (Battelle) and other CMOs' ability to develop and manufacture combination drug/device products and component parts based on our CAG technology for preclinical and clinical studies of our combination drug/device 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 and the APIs used in the manufacture of our drug product, CAG devices and related componentry and other materials on a timely basis or in an amount sufficient to support our needs;

- risks relating to our ability to manage our limited resources effectively and timely modify our business strategy as needed to respond to developments in our research and development activities, as well as in our business, our industry and other areas of concern;

- 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. (Deerfield), which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investments; moreover, we may be required to seek the consent of Deerfield to enter into certain strategic transactions;

- the risk that if we fail to regain compliance with the minimum closing bid price of $1.00 per share required under the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted and the value of our common stock may decrease; 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 16, 2015, 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 as a result 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, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,091	$ 44,711
Inventory, net	–	27
Prepaid expenses and other current assets	571	821
Total current assets	26,662	45,559
Property and equipment, net	1,245	1,637
Restricted cash	225	225
Other assets	68	78
Total assets	$ 28,200	$ 47,499
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,314	$ 350
Accrued expenses	6,613	6,116
Deferred revenue	–	43
Common stock warrant liability	820	1,258
Equipment loans, current portion	21	62
Total current liabilities	9,768	7,829
Long-term debt, $30,000 net of discount of $8,549 at June 30, 2015 and $9,698 at December 31, 2014	21,451	20,302
Other liabilities	59	169
Total liabilities	31,278	28,300
Stockholders' (Deficit) / 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 shares authorized; 85,937,481 and 85,607,806 shares issued at June 30, 2015 and December 31, 2014, respectively; 85,916,589 and 85,586,914 shares outstanding at June 30, 2015 and December 31, 2014, respectively	86	86
Additional paid-in capital	547,403	546,175
Accumulated deficit	(547,513)	(524,008)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total stockholders' (deficit) / equity	(3,078)	19,199
Total liabilities & stockholders' (deficit) / equity	$ 28,200	$ 47,499

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,	
	2015	**2014**	**2015**	**2014**
Revenues:				
Product sales	$ –	$ 42	$ 7	$ 70
Grant revenue	75	1,051	259	1,054
	75	1,093	266	1,124
Expenses:				
Cost of product sales	–	731	929	1,512
Research and development	7,129	6,858	14,211	12,448
Selling, general and administrative	3,383	4,446	6,736	8,869
	10,512	12,035	21,876	22,829
Operating loss	(10,437)	(10,942)	(21,610)	(21,705)
Change in fair value of common stock warrant liability	469	1,448	438	1,826
Other income / (expense):				
Interest and other income	1	2	234	4
Interest and other expense	(1,359)	(1,131)	(2,567)	(2,224)
Other income / (expense), net	(1,358)	(1,129)	(2,333)	(2,220)
Net loss	$ (11,326)	$ (10,623)	$ (23,505)	$ (22,099)
Net loss per common share				
Basic	$ (0.13)	$ (0.12)	$ (0.27)	$ (0.26)
Diluted	$ (0.13)	$ (0.14)	$ (0.27)	$ (0.28)
Weighted average number of common shares outstanding				
Basic	85,753	85,061	85,671	84,766
Diluted	85,753	85,882	85,671	86,111

See notes to consolidated financial statements.

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

(in thousands)

	Six Months Ended June 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (23,505)	$ (22,099)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	561	371
Change in provision for excess inventory	(174)	1,465
Stock-based compensation and 401(k) Plan employer match	1,228	1,975
Fair value adjustment of common stock warrants	(438)	(1,826)
Amortization of discount on long-term debt	1,149	909
Loss on sale of equipment	84	–
Changes in:		
Inventory	201	(2,196)
Accounts receivable	–	26
Prepaid expenses and other current assets	250	334
Accounts payable	1,964	74
Accrued expenses	497	1,166
Deferred revenue	(43)	(34)
Other liabilities	(110)	(423)
Net cash used in operating activities	(18,336)	(20,258)
Cash flows from investing activities:		
Purchase of property and equipment	(503)	(883)
Proceeds from sale of property and equipment	260	–
Net cash used in investing activities	(243)	(883)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	–	31
Proceeds from exercise of common stock warrants	–	423
Repayment of equipment loans	(41)	(39)
Net cash (used in) / provided by financing activities	(41)	415
Net decrease in cash and cash equivalents	(18,620)	(20,726)
Cash and cash equivalents – beginning of period	44,711	86,283
Cash and cash equivalents – end of period	$ 26,091	$ 65,557
Supplementary disclosure of cash flows information:		
Interest paid	$ 1,303	$ 1,305

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements (unaudited)

Note 1 – The Company and Description of Business

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases. Our proprietary technology platforms include a novel synthetic peptide-containing (KL4) surfactant, that is structurally similar to pulmonary surfactant, and proprietary drug delivery technologies being developed to enable efficient delivery of aerosolized KL4 surfactant. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. We believe that our proprietary technologies may make it possible to develop a pipeline of aerosolized surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our development programs have been focused initially 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 KL4 surfactant, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved in 2012 by the United States Food and Drug Administration (FDA) for the prevention of RDS in premature infants at high risk for RDS. In April 2015, we implemented a plan to voluntarily cease the commercialization of SURFAXIN and focus our resources on the development of aerosolized KL4 surfactant for respiratory diseases, beginning with AEROSURF® for RDS in premature infants.

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, invasive procedures that may each result in serious respiratory conditions and other complications. To avoid such complications, many neonatologists treat premature infants with less severe RDS using less invasive means, typically nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of premature infants will respond poorly to nCPAP (an outcome referred to as nCPAP failure) and may require delayed surfactant therapy. Since neonatologists cannot predict which infants are likely to experience nCPAP failure, neonatologists are faced with difficult choices in treating infants with less severe RDS. This is because the medical outcomes for 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 an investigational combination drug/device product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG) technology. With AEROSURF, neonatologists potentially will be able to administer aerosolized KL4 surfactant to premature infants supported with nCPAP alone, without having to resort to invasive intubation and mechanical ventilation. By enabling delivery of our aerosolized KL4 surfactant using less invasive means, we believe that AEROSURF will 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.

In May 2015, we announced the results of our AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age with RDS. This clinical trial was conducted in 48 premature infants 29 to 34 week gestational age who were receiving nCPAP for RDS and was an open label, single-dose study with the primary goal of evaluating the safety and tolerability of aerosolized KL4 surfactant administered in escalating inhaled doses in premature infants compared to infants receiving nCPAP alone. In addition to evaluating safety and tolerability, another key objective of this trial was to establish proof of concept for our proprietary technology platform with (1) physiological data indicating that aerosolized KL4 surfactant is being effectively delivered into the lung of premature infants, and (2) acceptable performance of the novel CAG technology in the NICU. All key objectives of this trial were met. We currently are conducting the next phases of our phase 2a clinical program, including: (i) we have completed enrollment of the first of two dose groups in an expansion study in 32 premature infants 29 to 34 week gestational age who are receiving nCPAP for RDS, primarily to evaluate safety and tolerability of aerosolized KL4 surfactant administered in higher (60 and 90 minutes) and repeat doses compared to nCPAP alone, and (ii) we expect to begin enrollment in August for a study in 32 premature infants 26 to 28 week gestational age receiving nCPAP for RDS, primarily to evaluate safety and tolerability of aerosolized KL4 surfactant administered in escalating (30 and 45 minutes) doses, with potential repeat doses, compared to nCPAP alone. In addition, as with the initial phase 2a study, we also are assessing performance of the CAG in the NICU and available physiological parameters for indications that aerosolized KL4 surfactant is being delivered to the lungs. We are also preparing for an AEROSURF phase 2b clinical trial, which is expected to be completed in mid-2016. The primary purpose of the phase 2b clinical trial will be to demonstrate evidence of efficacy on an acceptable endpoint, identify the dose regimen(s) to be used in the planned phase 3 clinical program and provide an estimate of the treatment effect (magnitude of benefit). We currently expect that the phase 2b trial will assess aerosolized KL4 surfactant administered in two escalating doses to 200 to 250 premature infants 26 to 32 week gestational age who are receiving nCPAP for RDS, compared to infants receiving nCPAP alone. We expect to conduct this trial in up to approximately 50 clinical sites within and outside the United States.

With the knowledge that we gain from our efforts to develop AEROSURF for the treatment of RDS in premature infants with RDS, we believe that we may be able to leverage our proprietary aerosolized KL_4 surfactant technology and our novel drug delivery technologies potentially to address serious critical care respiratory conditions affecting pediatric and adult patient populations. While we remain focused on RDS, we have explored and plan in the future to explore potential opportunities to address such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI, where there are no currently approved therapies other than supportive respiratory care. In addition, we may explore opportunities to apply KL_4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis. We believe that we have a potential opportunity to develop a broad pipeline of KL_4 surfactant products and that investment in these indications could potentially yield products that may be effective to address significant unmet medical needs that also could represent significant market opportunities.

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, committed equity financing facilities, at-the-market equity programs, and capital equipment financings. We expect to fund our business operations in the future primarily through all or a combination of strategic alliances, public equity offerings, including under our ATM Program (*see*, Note 10, "Stockholders' Equity – At-the-Market Program (ATM Program)," in the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2014 that we filed with the Securities and Exchange Commission (SEC) on March 16, 2015 (2014 Form 10-K)), the potential exercise of outstanding warrants, and secured debt facilities.

As of June 30, 2015, we had cash and cash equivalents of $26.1 million and long-term debt of $30 million under our loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 6, "Deerfield Loan."). On July 22, 2015, we completed a public offering of common stock, warrants and pre-funded warrants, resulting in gross proceeds to us of approximately $40.25 million ($37.6 million net after deducting underwriting fees and estimated expenses, and including $5.0 million in non-cash consideration from Deerfield in satisfaction of future interest payments under the Deerfield Loan). *See*, Note 8, "Subsequent Events – July 2015 Registered Public Offering." Under our ATM Program, subject to market conditions, we may sell up to approximately $23 million of common stock at such times and in such amounts we deem appropriate, subject to a 3% commission. To secure additional capital when needed, we also will consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions. There can be no assurance, however, that we will be successful in securing additional capital when needed, if at all. Before any additional financings and taking into account the impact of certain July 2015 amendments to the Deerfield Loan and the collaboration agreement with Battelle Memorial Institute (Battelle), discussed below, we anticipate that we will have sufficient cash available to support our AEROSURF phase 2 clinical program, pay our debt service obligations and fund our operations through the first quarter of 2017.

In July 2015, we entered into two amendments to the Deerfield Loan agreement and related notes (Deerfield Notes), pursuant to which (i) we prepaid in cash $5.0 million of the outstanding principal amounts under the Deerfield Notes; (ii) the payment dates for the remaining principal installments due under the Deerfield Loan were amended to (x) eliminate the installment due in February 2017, and (y) adjust the amounts due on each of February 13, 2018 and February 13, 2019 to $12.5 million and $12.5 million, respectively; (iii) in our July 2015 public offering, in lieu of providing cash consideration, Deerfield accepted $5 million securities issued thereunder in prepayment of $5 million future interest obligations under the Deerfield Notes allocated in the manner provided in the amendment; and (iv) following application of the full $5 million interest prepayments described in clause (iii), the interest rate on any remaining interest due under the Deerfield Notes was adjusted from 8.75% to 8.25%.

Under our collaboration agreement with Battelle, we have completed Stage 1 (design requirements) of the three-stage project plan to develop our CAG device for potential use in our AEROSURF phase 3 clinical program and, if approved, initial commercial supply. In July 2015, we agreed on a planned cost of up to approximately $11.85 million to complete Stage 2 (development) and Stage 3 (design verification and testing) of the project plan, which under the collaboration agreement will be shared equally. Accordingly, we expect our 50% share of the planned cost for Stage 2 and Stage 3 to be up to approximately $6 million and that, following the completion of Stage 3 in mid-2016, we will be in a position to manufacture the CAG device and related componentry for use in the AEROSURF phase 3 clinical program. There can be no assurance that our collaboration will be successful or that we will timely complete the development work within the anticipated time, if ever, and for the anticipated cost contemplated under the collaboration project plan. Under the collaboration agreement, we also may defer payments due to Battelle for up to 12 months, provided that (i) any amounts deferred will bear interest from and after 90 days at a rate of 12% per annum, and (ii) the aggregate amounts deferred more than 30 days may not exceed at any time our available cash and cash equivalents. We currently have deferred $1.5 million and expect to defer aggregate payments of up to approximately $4.0 million at certain times throughout the term of the project.

For at least the next several years, we do not expect to generate any revenue from the sale of approved products. Thus, to secure the significant additional infusions of capital that we will need to execute our business strategy, advance our development programs, pay debt obligations and fund our operations, we will have to rely on non-sales sources of capital, including potentially: (i) strategic alliances and collaboration arrangements, which could provide development and commercial expertise to support the development and, if approved, commercial introduction of, our KL4 surfactant pipeline product candidates, beginning with AEROSURF, in 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. We believe that we will be better positioned to identify and enter into a significant strategic alliance for AEROSURF if we obtain encouraging results from the AEROSURF phase 2 clinical program; (ii) public and private equity offerings, including potentially pursuant to our ATM Program; (iii) secured debt arrangements to provide working capital and fund investment in capital assets; and (iv) the potential exercise of outstanding warrants (discussed below). In addition, we have in the past collaborated with research organizations and universities to assess potential application of our KL4 surfactant in studies funded in part through various U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical program and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological, and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. Although there can be no assurance, we expect that we may have opportunities in the future to participate in similar programs.

As of June 30, 2015, we had outstanding warrants to purchase approximately 13.2 million shares of our common stock at various prices, exercisable on different dates into 2024. This includes warrants to purchase up to 7.0 million shares that were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share (Deerfield Warrants). The Deerfield Warrants may be exercised for cash or through a net cashless exercise. 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 expire in February 2016 and 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-current exercise price of the warrants. The exercise price of these warrants was recently adjusted as a result of our July 2015 public offering and currently have an exercise price of $0.19 per share. If the holders determine in their discretion to exercise the February 2011 warrants prior to their expiration date in February 2016 (and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants), we potentially could receive up to approximately $0.9 million. In addition, in connection with the July 2015 public offering, we issued warrants to purchase up to approximately 67.1 million shares of common stock at an initial exercise price of $0.70 per share, and 42.0 million fully paid pre-funded warrants to purchase one share of common stock at an exercise price of $0.60 per share. The July 2015 warrants may be exercised at the election of the holder for cash or through a net cashless exercise. There can be no assurance that the price of our common stock will achieve a level greater than the exercise price of the Deerfield Warrants or the July 2015 warrants, that the holders 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. If any of 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. Moreover, if the holders of the February 2011 warrants choose to exercise their warrants at any time prior to the expiration date in February 2016, such exercises could be accompanied by increased selling activity in the Nasdaq market and the market value of our common stock could decline.

As of June 30, 2015, there were 250 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 136.0 million shares of common stock were available for issuance and not otherwise reserved. Of the 250 million shares of common stock that are presently authorized under our Amended and Restated Certificate of Incorporation, as amended, as of July 22, 2015, approximately 246.9 million shares of common stock are either issued and outstanding or reserved for issuance under our 2011 Equity Incentive Plans (2011 Plan), our 401(k) benefit plan, and upon exercise of outstanding warrants. If in the future we are unable to fund our capital requirements, we will not have sufficient cash flows and liquidity to fund our business operations and pay our debt service. In that event, we may be forced to further limit our development programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to secure additional capital, such transactions may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Moreover, if we fail in the future to make any required payment under our Deerfield Loan or fail to comply with any commitments contained in the loan documents, Deerfield would be able to declare us in default regarding that indebtedness, which could result in the acceleration of the payment obligations under all or a portion of our indebtedness. Since we have pledged substantially all of our assets to secure our obligations under the Deerfield Loan, a debt default would enable the lenders to foreclose on our assets securing the debt and could significantly diminish the market value and marketability of our common stock. Our financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

On June 29, 2015, we received a letter from The Nasdaq Stock Market indicating that for 30 consecutive business days our common stock had not maintained a minimum closing per share bid price of $1.00 ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). This notification had no immediate impact on the continued trading or listing of our common stock on Nasdaq. Under Nasdaq's Listing Rules, we have 180 calendar days from the date of the notification (the "Compliance Period"), or until December 28, 2015, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the closing bid price of our common stock must close above $1.00 for a minimum of 10 consecutive business days; thereafter, our common stock would continue to be eligible for listing on the Nasdaq Capital Market. If we are unable to achieve compliance with the Minimum Bid Price Requirement within 180 days, we may be eligible for a 180-day extension of the Compliance Period if we meet certain criteria set forth in the Nasdaq Listing Rules. If we fail to achieve compliance with the Minimum Bid Price Requirement within the applicable Compliance Period, the Nasdaq staff would issue a delisting notification and we would be subject to potential delisting, which if it occurred likely would further impair the liquidity and value of our common stock.

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. 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, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. There have been no changes to our critical accounting policies since December 31, 2014. For a discussion of our accounting policies, *see*, Note 3, "Accounting Policies and Recent Accounting Pronouncements," in the Notes to Consolidated Financial Statements in our 2014 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Use of Estimates

The preparation of financial statements, in conformity with accounting principles generally accepted in the U.S., requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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.

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 provided for severance for non-union employees and retention bonuses for management. An additional 12 employees were subject to a collective bargaining agreement under which they were eligible to receive severance payments when the Totowa Facility closed.

In April 2015, we implemented a restructuring plan to voluntarily cease the commercialization of SURFAXIN and focus our resources on the development of our aerosolized KL4 surfactant pipeline for respiratory diseases, beginning with AEROSURF. As part of the restructuring plan, we ceased manufacturing activities at our Totowa Facility, which we closed upon the expiration of our lease on June 30, 2015.

The severance cost for all impacted employees is $2.9 million, of which $1.1 million was accrued as of March 31, 2015 for Totowa employees under the September 2013 severance and retention plan. The remaining $1.8 million was charged during the three months ended June 30, 2015 ($0.9 million to research and development expenses and $0.9 million to selling, general and administrative expenses). We paid $1.8 million of the severance and retention benefits during the three months ended June 30, 2015. The remaining $1.1 million will be paid through June 30, 2016.

Long-lived assets

Our long-lived assets, primarily consisting of manufacturing and laboratory equipment, are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable, or its estimated useful life has changed significantly. When the undiscounted cash flows of an asset are less than its carrying value, an impairment is recorded and the asset is written down to estimated value. In the second quarter of 2015, we closed the Totowa Facility and sold manufacturing equipment for total cash proceeds of $0.3 million, resulting in a $0.1 million loss from the sale and disposal of these assets.

Research and development expense

We account for research and development expense by the following categories: (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, 2015 and 2014, the number of shares of common stock potentially issuable upon the exercise of stock options and warrants was 21.3 million and 20.9 million shares, respectively. As of June 30, 2015 and 2014, 21.3 million and 16.4 million shares of common stock potentially issuable upon the exercise of stock options and warrants were excluded from the computation of diluted net loss per common share because their impact would have been anti-dilutive.

In accordance with Accounting Standards Codification Topic 260 (ASC 260), *Earnings per Share*, when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of warrants classified as derivative liabilities results in an adjustment to the net loss; and the dilutive impact of the assumed exercise of these 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 warrants classified as derivative liabilities.

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	**2014**	**2015**	**2014**
Numerator:				
Net loss as reported	$ (11,326)	$ (10,623)	$ (23,505)	$ (22,099)
Less: income from change in fair value of warrant liability	(469)	(1,447)	(438)	(1,820)
Numerator for diluted net loss per common share	$ (11,795)	$ (12,070)	$ (23,943)	$ (23,919)
Denominator:				
Basic weighted average common shares outstanding	85,753	85,061	85,671	84,766
Dilutive common shares from assumed warrant exercises	–	821	–	1,345
Diluted weighted average common shares outstanding	85,753	85,882	85,671	86,111

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

Recent accounting pronouncements

In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*, which requires an entity to present debt issuance costs in the balance sheet as a direct deduction from the carrying amount of the corresponding debt liability, consistent with debt discounts. The guidance would not address situations in which debt issuance costs do not have an associated debt liability or exceed the carrying amount of the associated debt liability (e.g., an undrawn or partially drawn line of credit). The new standard is effective for us in the annual period ending December 31, 2016, including interim periods within that annual period. Early adoption is permitted and the standard is to be applied retrospectively. We are evaluating the effect that ASU 2015-03 will have on our consolidated financial statements and related disclosures.

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, 2015	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 26,091	$ 26,091	$ –	$ –
Certificate of deposit	225	225	–	–
Total Assets	$ 26,316	$ 26,316	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 820	$ –	$ –	$ 820

	Fair Value December 31, 2014	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 44,711	$ 44,711	$ –	$ –
Certificate of deposit	225	225	–	–
Total Assets	$ 44,936	$ 44,936	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 1,258	$ –	$ –	$ 1,258

The table below summarizes the activity of Level 3 inputs measured on a recurring basis for the six months ended June 30, 2015 and 2014:

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2014	$ 1,258
Change in fair value of common stock warrant liability	(438)
Balance at June 30, 2015	$ 820

(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

The significant unobservable inputs for a trinomial model 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 certain of the warrants. 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, 2015	December 31, 2014
Historical volatility	82%	55% – 84%
Expected term (in years)	0.6	0.1 – 1.1
Risk-free interest rate	0.16%	0.03% – 0.31%

Fair Value of Long-Term Debt

At June 30, 2015, the estimated fair value of the Deerfield Loan (*see*, Note 6, "Deerfield Loan") was $21.4 million compared to a carrying value, net of discounts, of $21.5 million. At December 31, 2014, the estimated fair value of the Deerfield Loan was $22.2 million compared to a carrying value, net of discounts, of $20.3 million. The estimated fair value of the Deerfield Loan is based on discounting the future contractual cash flows to the present value at the valuation date. 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 we could realize 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 – 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.

On February 22, 2011, we issued registered warrants that expire on February 22, 2016 and had a fair value at issuance of $8.0 million. As of June 30, 2015, there were 4.6 million warrant shares with a fair value of $0.8 million potentially issuable upon exercise of these warrants. These warrants 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. Although by their express terms, these warrants are not subject to potential cash settlement, due to the nature of the anti-dilution provisions, they are classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model. The exercise price of these warrants as of June 30, 2015 was $1.50 per share. The exercise price was recently adjusted to $0.19 per share in connection with our July 2015 public offering (*see*, Note 8, "Subsequent Events – July 2015 Registered Public Offering"). 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."

No warrants were exercised during the six months ended June 30, 2015. 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.

Note 6 – Deerfield Loan

Long-term debt consists solely of amounts due under the Deerfield Loan for the periods presented:

(in thousands)	June 30, 2015	December 31, 2014
Note payable	$ 30,000	$ 30,000
Unamortized discount	(8,549)	(9,698)
Long-term debt, net of discount	$ 21,451	$ 20,302

When issued, the principal amount of the loan was payable in three $10 million annual installments beginning in February 2017, provided that the installments due in February 2017 and 2018 could be deferred one year if prior to such payment date we achieve a certain market capitalization milestone. *See*, Note 9, "Deerfield Loan," in the Notes to Consolidated Financial Statements in our 2014 Form 10-K. Accordingly, if the milestones were achieved in each year, payment of the principal amount could be deferred until the sixth anniversary date of the loan on February 13, 2019. In July 2015, we restructured the Deerfield Loan by prepaying $5.0 million of the outstanding principal amount, prepaying (in the form of securities issued in the July 2015 public offering) $5.0 million in future interest obligations, reducing the interest rate on remaining interest from 8.75% to 8.25%, eliminating the installment due in February 2017 and adjusting the remaining maturities. (s*ee*, Note 8, "Subsequent Events – Deerfield Loan Restructuring")

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,	
	2015	2014	2015	2014
Cash interest expense	$ 654	$ 654	$ 1,301	$ 1,302
Non-cash amortization of debt discounts	594	470	1,149	909
Amortization of debt costs	5	5	10	10
Total interest expense	$ 1,253	$ 1,129	$ 2,460	$ 2,221

Cash interest expense represents interest at an annual rate of 8.75% 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 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 Deerfield Loan, we issued the 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," in the Notes to Consolidated Financial Statements in our 2014 Form 10-K.

Note 7 – 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,	
	2015	**2014**
Weighted average expected volatility	83%	100%
Weighted average expected term	5.6 years	5.4 years
Weighted average risk-free interest rate	1.5%	1.6%
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,	
	2015	**2014**	**2015**	**2014**
Research & development	$ 146	$ 299	$ 359	$ 547
Selling, general & administrative	189	482	575	938
Total	$ 335	$ 781	$ 934	$ 1,485

Note 8 – Subsequent Event

We evaluated all events or transactions that occurred after June 30, 2015 through the date we issued these financial statements. During this period, we noted two subsequent events as described below:

July 2015 Registered Public Offering

On July 22, 2015, we completed a registered public offering of 25,083,332 Series A units and 42,000,000 Series B units each at a price per unit of $0.60, resulting in gross proceeds of $40.25 million ($37.6 million net after underwriting discount and estimated expenses), including the exercise in full by the underwriters of their option to purchase up to an additional 8,749,999 Series A units at a price per unit of $0.60 to cover over-allotments. The proceeds included $5.0 million in non-cash consideration from Deerfield in the form of a reduction in future interest payments due under the Deerfield Loan (*see*, "– Deerfield Loan Restructuring"). Each Series A unit consists of one share of common stock and a Series A warrant to purchase one share of common stock at an exercise price of $.70 per share. Each Series B unit consists of a fully paid pre-funded Series B warrant to purchase one share of common stock at an exercise price of $0.60 per share, and a Series B warrant to purchase one share of common stock at an exercise price of $.70 per share. The shares of common stock and warrants were immediately separable such that no units were issued. The warrants are exercisable immediately at the election of the holder for cash or through a net cashless exercise, provided that a holder may not exercise a warrant to the extent that after giving effect to such exercise, such holder would beneficially own in excess of 9.99% (or 4.99% as may be elected by such holder) of the shares of our common stock outstanding immediately after such exercise. All warrants will expire on the seventh anniversary of the issue date. The net proceeds will be used primarily (i) to advance the AEROSURF development program, and (ii) for general corporate purposes.

As the offering price in the July 2015 registered public offering ($0.60 per unit) was less than the then-current exercise price of the warrants we issued in a February 2011 public offering ($1.50 per share), the exercise price of the February 2011 warrants was adjusted in accordance with anti-dilution provisions contained in the warrant, which 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. For a unit offering consisting of common stock and warrants, the terms of the February 2011 warrants provide that the common stock will be deemed to have been issued at a price per share equal to the difference between the aggregate consideration received ($0.60 per unit) less the value of the option determined using a Black Scholes option pricing model calculated using criteria and measured over the period set forth in the warrant. Based on these requirements, upon the closing of the July 2015 public offering, the exercise price of the February 2011 warrants was adjusted to $0.19 per share. There are currently outstanding 4.6 million February 2011 warrants which will expire in February 2016.

Deerfield Loan Restructuring

On July 9, 2015, we entered into an amendment to our Deerfield Loan agreement and Deerfield Notes to better align our Deerfield Loan principal repayment obligations with anticipated milestones under our clinical development program for AEROSURF. Under the terms of the amendment, upon execution, we prepaid in cash $2.5 million of the outstanding principal amounts under the Deerfield Loan. If within five business days after completion of a Strategic Transaction (as defined in the amendment) on or before December 31, 2015, we were to prepay an additional $2.5 million to be applied to the outstanding principal amounts, then the installment due in February 2017 would be eliminated and the installments due in each of February 2018 and 2019 would be adjusted to $12.5 million and $12.5 million, respectively. We also agreed to pay Deerfield's expenses (including reasonable counsel fees and expenses of up to $15,000) incurred in connection with the amendment. All terms of the Deerfield Loan agreement and Deerfield Notes not otherwise amended remained in full force and effect.

On July 22, 2015, Deerfield and we entered into a second amendment to the Deerfield Loan agreement and Deerfield Notes. Under the second amendment, we agreed, upon the closing of the July 2015 offering, to effect the prepayment in cash of $2.5 million contemplated by the first amendment to be applied to the outstanding principal amounts due under the Deerfield Notes, and Deerfield agreed to purchase and accept $5 million of Series A and Series B units in the July 2015 public offering in satisfaction of $5 million of future interest obligations due to Deerfield under the Deerfield Loan agreement. Pursuant to the second amendment: (i) we agreed to pay in cash all accrued and unpaid interest on the Deerfield Loan for the period from June 30, 2015 to July 22, 2015 at the existing rate of 8.75% when due on September 30, 2015; (ii) the $5 million prepayment of interest will be applied, first, to interest accruing from and after July 23, 2015 on the $12.5 million principal installment due on February 13, 2019, and thereafter dollar for dollar to interest accruing from and after July 23, 2015 on the $12.5 million principal installment due on February 13, 2018, until fully allocated; and (iii) after such interest prepayment is fully allocated, any remaining interest due on the principal amount of the Deerfield Notes will thereafter accrue at a rate of 8.25% per annum and payable as otherwise provided in the Deerfield Loan agreement and Deerfield Notes. In addition, no credit will be given with respect to prepaid interest for periods subsequent to the date of a principal prepayment as a result of the voluntary or mandatory prepayment of the Deerfield Notes, in whole or in part, except for a prepayment at our election or a required prepayment in connection with a major transaction under and as defined in the Deerfield Loan agreement, in either case, in connection with a Qualified Major Transaction, which is defined as a change of control (as defined in the Deerfield Loan agreement) in which (i) we are not the surviving entity and (ii) our common stock valuation immediately prior to the change of control, equals or exceeds $100 million. All terms of the Deerfield Loan agreement and Deerfield Notes not otherwise amended remained in full force and effect.

The July 2015 public offering that we completed on July 22, 2015 qualified as a Strategic Transaction under the first amendment to the Deerfield Loan agreement. Accordingly, on July 22, 2015, we prepaid in cash an additional $2.5 million to be applied to the outstanding principal amount due under the Deerfield Loan agreement. Pursuant to the first amendment, upon such payment, the February 2017 installment has been eliminated and the installments due in each of February 2018 and 2019 have been adjusted to $12.5 million and $12.5 million, respectively. In addition, the $12.5 million installment currently due in February 2018 remains subject to potential deferral of one year if we achieve the market capitalization milestone set forth in the Deerfield Loan agreement (*see*, Note 6, "Deerfield Loan"). Pursuant to the terms of the second amendment, we have prepaid all interest due on the $12.5 million principal installment due on February 13, 2019 through the maturity date and interest due on the $12.5 million principal installment due on February 13, 2018 through the second quarter of 2016.

Common shares reserved for potential future issuance upon exercise of warrants

The chart below summarizes shares of our common stock reserved for future issuance upon the exercise of warrants as of July 22, 2015:

(in thousands, except price per share data)	Shares	Exercise Price	Expiration Date
Investors – February 2011 financing	4,550	$ 0.19	2/22/16
Investors – July 2015 financing (pre-funded) (1)	42,000	$ 0.60	7/22/22
Investors – July 2015 financing	67,083	$ 0.70	7/22/22
Deerfield – 2013 loan	7,000	$ 2.81	2/13/19
Battelle – 2014 collaboration agreement	1,500	$ 5.00	10/10/24
Former employee	30	$ 3.20	3/18/16
PharmaBio – October 2010 financing	80	$ 4.10	10/13/15
Kingsbridge – June 2010 CEFF	83	$ 6.69	12/11/15
	122,326		

(1) Investors in these warrants fully prepaid the $0.60 exercise price at the time of issuance.

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 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, 2014 that we filed with the Securities and Exchange Commission (SEC) on March 16, 2015 (2014 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). Unless otherwise specified, references to Notes in this MD&A shall refer to the Notes to Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q

OVERVIEW

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases. Our proprietary technology platforms include a novel synthetic peptide-containing (KL4) surfactant, that is structurally similar to pulmonary surfactant, and proprietary drug delivery technologies being developed to enable efficient delivery of aerosolized KL4 surfactant. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. We believe that our proprietary technologies may make it possible to develop a pipeline of aerosolized surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our development programs have been focused initially 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 KL4 surfactant, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved in 2012 by the United States Food and Drug Administration (FDA) for the prevention of RDS in premature infants at high risk for RDS. In April 2015, we implemented a plan to voluntarily cease the commercialization of SURFAXIN and focus our resources on the development of aerosolized KL4 surfactant for respiratory diseases, beginning with AEROSURF® for RDS in premature infants.

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, invasive procedures that may each result in serious respiratory conditions and other complications. To avoid such complications, many neonatologists treat premature infants with less severe RDS using less invasive means, typically nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of premature infants will respond poorly to nCPAP (an outcome referred to as nCPAP failure) and may require delayed surfactant therapy. Since neonatologists cannot predict which infants are likely to experience nCPAP failure, neonatologists are faced with difficult choices in treating infants with less severe RDS. This is because the medical outcomes for 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 an investigational combination drug/device product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG) technology. With AEROSURF, neonatologists potentially will be able to administer aerosolized KL4 surfactant to premature infants supported with nCPAP alone, without having to resort to invasive intubation and mechanical ventilation. By enabling delivery of our aerosolized KL4 surfactant using less invasive means, we believe that AEROSURF will 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.

In May 2015, we announced the results of our AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age with RDS. This clinical trial was conducted in 48 premature infants 29 to 34 week gestational age who were receiving nCPAP for RDS and was an open label, single-dose study with the primary goal of evaluating the safety and tolerability of aerosolized KL4 surfactant administered in escalating inhaled doses in premature infants compared to infants receiving nCPAP alone. In addition to evaluating safety and tolerability, another key objective of this trial was to establish proof of concept for our proprietary technology platform with (1) physiological data indicating that aerosolized KL4 surfactant is being effectively delivered into the lung of premature infants, and (2) acceptable performance of the novel CAG technology in the NICU. All key objectives of this trial were met. See, "– Business and Pipeline Program Updates."

With the knowledge that we gain from our efforts to develop AEROSURF for the treatment of RDS in premature infants with RDS, we believe that we may be able to leverage our proprietary aerosolized KL4 surfactant technology and our novel drug delivery technologies potentially to address serious critical care respiratory conditions affecting pediatric and adult patient populations. While we remain focused on RDS, we have explored and plan in the future to explore potential opportunities to address such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI, where there are no currently approved therapies other than supportive respiratory care. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis. We believe that we have a potential opportunity to develop a broad pipeline of KL4 surfactant products and that investment in these indications could potentially yield products that may be effective to address significant unmet medical needs that also could represent significant market opportunities.

Business and Pipeline Program Updates

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business," in our Annual Report on Form 10-K for the year ended December 31, 2014 that we filed with the SEC on March 16, 2015 (2014 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 products and pipeline programs since the filing of our 2014 Form 10-K:

- For our AEROSURF clinical development program, we currently are conducting or preparing to initiate the following phase 2a clinical studies:

    (i) we have completed enrollment in the first of two dose groups in an expansion study in 32 premature infants 29 to 34 week gestational age who are receiving nCPAP for RDS, primarily to evaluate safety and tolerability of aerosolized KL4 surfactant administered in higher (60 and 90 minutes) and repeat doses compared to nCPAP alone, and

(ii) we expect to begin enrollment in August for a study in 32 premature infants 26 to 28 week gestational age receiving nCPAP for RDS, primarily to evaluate safety and tolerability of aerosolized KL_4 surfactant administered in escalating (30 and 45 minutes) doses, with potential repeat doses, compared to nCPAP alone.

In addition, as with the initial phase 2a study, we also are assessing in these studies performance of the CAG in the NICU and available physiological parameters for indications that aerosolized KL_4 surfactant is being delivered to the lungs. We expect that these studies will be completed in the fourth quarter of 2015.

- We are also preparing for an AEROSURF phase 2b clinical trial, which is expected to be completed in mid-2016. The primary purpose of the phase 2b clinical trial will be to demonstrate evidence of efficacy on an acceptable endpoint, identify the dose regimen(s) to be used in the planned phase 3 clinical program and provide an estimate of the treatment effect (magnitude of benefit). We currently expect that this trial will enroll 200 to 250 premature infants and will assess aerosolized KL_4 surfactant administered to premature infants 26 to 32 week gestational age who are receiving nCPAP for RDS in two escalating doses, compared to infants receiving nCPAP alone. We expect to conduct this trial in up to approximately 50 clinical sites within and outside the United States.

- We continue our work with Battelle Memorial Institute (Battelle) to provide for the manufacture of a sufficient number of CAG devices and disposable AEROSURF dose packs (ADPs) to support the remainder of our phase 2 clinical program.

- We are also advancing our development activities under our October 2014 collaboration agreement with Battelle to further develop our CAG device for use in our planned phase 3 clinical program and, if AEROSURF is approved, initial commercial activities. Battelle and we have completed the Stage 1 activities (design requirements) and recently agreed upon a project plan and anticipated costs of up to approximately $11.85 million for Stage 2 (development activities) and Stage 3 (design verification and testing) activities, which we will share equally under the collaboration agreement. We also agreed to amend our collaboration agreement to change the definition of Milestone Date for the date of completion of the Stage 3 activities, from May 31, 2016 to July 15, 2016. Under the collaboration, we will be responsible for one-half of the planned costs for Stage 2 and Stage 3. We currently expect that our share of the Stage 2 / Stage 3 development costs will be up to approximately $6.0 million, with Battelle contributing a similar amount.

- We continue to work with Patheon Manufacturing Services LLC (Patheon, formerly DSM Pharmaceuticals, Inc.) to complete a technology transfer of our lyophilized KL_4 surfactant manufacturing process and complete early manufacturing development activities for our lyophilized KL_4 surfactant. We plan to manufacture additional clinical supply to support the remainder of our phase 2 clinical program and have entered into a development agreement for the potential further development and manufacture of lyophilized KL_4 surfactant for our potential AEROSURF phase 3 clinical program, as well as other potential pipeline development programs. In addition, we are advised that Patheon intends to close the building in which our development activities have occurred. Accordingly, we are engaged in a technology transfer of our manufacturing process to a new facility within Patheon where the phase 3 manufacturing development work will occur.

- During the first quarter of 2015, we evaluated available potential strategic alternatives for SURFAXIN, the first synthetic, peptide-containing surfactant approved by the FDA, potentially to support our ongoing efforts to commercialize SURFAXIN and offset the rate of cash outflows that we were experiencing to support manufacturing, quality systems, supply chain and distribution, marketing, medical and commercial activities for SURFAXIN. In April, we concluded that none of the available alternatives could be accomplished on acceptable terms within a reasonable period and announced that we were implementing a restructuring plan (April 2015 Restructuring) to voluntarily cease commercialization of SURFAXIN to conserve our resources to advance the AEROSURF clinical program. In connection with this decision, we reduced our workforce by approximately 50 percent, ceased our manufacturing activities at our manufacturing facility in Totowa, NJ, and determined to allow our real property lease for our manufacturing facility in Totowa, NJ, to expire on June 30, 2015 in accordance with its terms. In addition, as a consequence of these actions, we are no longer considering in the near term a potential development plan to gain approval for SURFAXIN LS™, our lyophilized KL_4 surfactant, as a life-cycle extension of SURFAXIN.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2014. For a discussion of our accounting policies, *see*, Note 3, “Accounting Policies and Recent Accounting Pronouncements,” in the Notes to Consolidated Financial Statements (Notes) in our 2014 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the three months ended June 30, 2015 and 2014 was $11.3 million (or $0.13 basic net loss per share) and $10.6 million (or $0.12 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 $0.5 million and $1.4 million for 2015 and 2014, respectively, and (ii) interest expense of $1.3 million and $1.1 million for 2015 and 2014, respectively, associated with the Deerfield Loan.

The net loss for the six months ended June 30, 2015 and 2014 was $23.5 million (or $0.27 basic net loss per share) and $22.1 million (or $0.26 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 $0.4 million and $1.8 million for 2015 and 2014, respectively, and (ii) interest expense of $2.5 million and $2.2 million for 2015 and 2014, respectively, associated with the Deerfield Loan.

The operating loss for the three months ended June 30, 2015 and 2014 was $10.4 million and $10.9 million, respectively. The decrease in operating loss from 2014 to 2015 was due to a $1.0 million decrease in grant revenues offset by a $1.5 million decrease in operating expenses.

The operating loss for the six months ended June 30, 2015 and 2014 was $21.6 million and $21.7 million, respectively. The decrease in operating loss from 2014 to 2015 was due to a $0.8 million decrease in grant revenues offset by a $1.0 million decrease in operating expenses.

Grant Revenue

We recognized grant revenue of $0.1 million and $1.1 million for the three months ended June 30, 2015 and 2014, respectively, and $0.3 million and $1.1 million for the six months ended June 30, 2015 and 2014, respectively.

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. We received and expended $1.8 million in 2014 under this award and the received and expended the remaining award amount in the first quarter of 2015.

During the second quarter of 2015, we were awarded an additional $1.0 million under a previously awarded Phase II SBIR grant from the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH valued at up to $3.0 million over three years to support continued development of the company's aerosolized KL_4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury. We were awarded an initial $1.0 million under this grant during the third quarter of 2014. Under the initial award, we received and expended $0.7 million in 2014 and $0.2 million during the six months ended June 30, 2015. In the third quarter of 2015, we expect to receive the balance of that initial award and begin to receive and expend under the additional $1.0 million awarded in the second quarter of 2015. Additionally, next year we may be eligible for a third award of up to an additional $1.0 million following completion of certain research activities.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we account for such costs by category rather than by project. As many of our research and development activities form the foundation for the development of our KL_4 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 primarily of expenses associated with (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs.

Research and development expenses by category for the three and six months ended June 30, 2015 and 2014 are as follows:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Product development and manufacturing	$ 4,113	$ 3,298	$ 8,199	$ 6,922
Medical and regulatory operations	1,652	2,214	3,426	3,847
Direct preclinical and clinical programs	1,364	1,346	2,586	1,679
Total research & development expenses	$ 7,129	$ 6,858	$ 14,211	$ 12,448

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.3 million and $0.5 million for the three months ended June 30, 2015 and 2014, respectively, and of $0.7 million and $0.9 million for the six months ended June 30, 2015 and 2014, respectively.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with CMOs, validation activities, quality assurance and analytical chemistry capabilities that support the manufacture of our KL4 surfactant used in research and development activities, and our medical devices, including our CAG, (ii) design and development activities related to our CAG device for use in our AEROSURF 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, 2015 increased $0.8 million compared to the same period in 2014, due to an investment in 2015 of $0.8 million in development activities under our collaboration agreement with Battelle for the further development of our CAG for use in our planned phase 3 clinical program for AEROSURF and, if approved, initial commercial activities.

Product development and manufacturing expenses for the six months ended June 30, 2015 increased $1.3 million compared to the same period in 2014, due to an investment of $1.3 million in 2015 for development activities under our collaboration agreement with Battelle for the further development of our CAG for use in our planned phase 3 clinical program for AEROSURF and, if approved, initial commercial activities.

Medical and Regulatory Operations

Medical and regulatory operations includes (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our research and development programs; and (ii) medical affairs activities to provide scientific and medical education support for our 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, 2015 decreased $0.6 million compared to the same period in 2014 due to a $0.8 million decrease in medical affairs related to the April 2015 Restructuring, partially offset by a $0.2 million increase related to our preclinical and clinical capabilities to support our AEROSURF development program.

Medical and regulatory operations expenses for the six months ended June 30, 2015 decreased $0.4 million compared to the same period in 2014 due to a $0.9 million decrease in medical affairs activities related to the April 2015 Restructuring and our efforts during the first quarter of 2015 to limit medical affairs expenses while we evaluated potential strategic alternatives for SURFAXIN, partially offset by a $0.4 million increase related to our preclinical and clinical capabilities to support our AEROSURF development program.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) development activities, toxicology studies and other preclinical studies; and (ii) activities associated with conducting clinical trials, including patient enrollment costs, clinical site costs, clinical device and drug supply, and related external costs, such as consultant fees and expenses.

Direct preclinical and clinical programs expenses were comparable for the three months ended June 30, 2015 and 2014. Investment in our AEROSURF clinical trial activities increased $0.4 million in 2015 compared to the same period in 2014 due to ongoing patient enrollment in the Phase 2a clinical study and the manufacture of clinic-ready CAG devices to support further clinical activities, including the planned AEROSURF Phase 2b clinical trial, offset by a $0.4 million decrease in preclinical studies.

Direct preclinical and clinical programs expenses for the six months ended June 30, 2015 increased $0.9 million compared to the same period in 2014 due to a $1.3 million increase in AEROSURF clinical trial activities, including ongoing patient enrollment in the Phase 2a study and manufacture of clinic-ready CAG devices to support further clinical activities, including the planned AEROSURF Phase 2b clinical trial, partially offset by a $0.4 million decrease in preclinical studies.

If our early clinical results are encouraging, we anticipate that our direct clinical program costs will increase significantly over the next few years as we refine our development plan for AEROSURF and execute the later stages of the AEROSURF clinical development program. If successful, we estimate incurring $15 to $20 million in 2015 and 2016 on direct clinical program costs for the AEROSURF phase 2 program.

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 our 2014 Form 10-K, including in “Item 1 – Business – Government Regulation,” “Item 1A – Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Research and Development Expenses.”

Our lead research and development projects for aerosolized KL_4 surfactant are focused initially on the management of RDS in premature infants. They currently include (i) AEROSURF phase 2 clinical trial activities and preparatory work for the planned AEROSURF phase 3 clinical program; (ii) our aerosol delivery technologies development, including our CAG device, which currently is being used in our AEROSURF phase 2 clinical program. In addition, under our collaboration agreement with Battelle, we and Battelle have agreed to share equally in the planned cost of a project to further develop our CAG device for use in our planned AEROSURF phase 3 clinical program and, if approved, initial commercial activities; and (iii) lyophilized KL_4 surfactant, which we are developing initially for use in our AEROSURF development program.

To support our ongoing AEROSURF phase 2a clinical program, our planned phase 2b clinical trial and our planned phase 3 clinical program, we plan to make additional investments in our development capabilities, including for (i) manufacturing development of our lyophilized KL_4 surfactant, (ii) manufacture of additional CAG devices to support our phase 2 clinical program, (iii) further development of our CAG device under our collaboration with Battelle for our planned phase 3 clinical program, (iv) manufacture of phase 3 CAG devices to support our phase 3 clinical program and if AEROSURF is approved, initial commercial activities, and (v) the conduct of these planned clinical trials. In particular, we anticipate that direct clinical program costs for AEROSURF will increase significantly over the next few years as we assess the results of our phase 2a clinical program and initiate and execute the later stages of the planned AEROSURF clinical development program.

During the second quarter, we announced the results of our AEROSURF phase 2a clinical trial in 48 premature infants 29 to 34 week gestational age with RDS who were receiving nCPAP for RDS and was an open label, single-dose study with the primary goal of evaluating the safety and tolerability of aerosolized KL_4 surfactant administered in escalating inhaled doses in premature infants compared to infants receiving nCPAP alone. In addition to evaluating safety and tolerability, another key objective of this trial is to establish proof of concept for our proprietary technology platform with (1) physiological data indicating that aerosolized KL_4 surfactant is being effectively delivered into the lung of premature infants, and (2) acceptable performance of the novel CAG technology in the NICU. *See*, “– Overview.” In addition, we have completed enrollment of the first of two dose groups in a phase 2a clinical study of 32 premature infants 29 to 34 week gestational age who are receiving nCPAP for RDS with the primary objective to evaluate safety and tolerability of aerosolized KL_4 surfactant, primarily to evaluate safety and tolerability of aerosolized KL_4 surfactant administered in higher (60 and 90 minutes) and repeat doses compared to nCPAP alone, and we expect to initiate in August 2015 a study in 32 premature infants 26 to 28 week gestational age receiving nCPAP for RDS, primarily to evaluate safety and tolerability of aerosolized KL_4 surfactant administered in escalating (30 and 45 minutes) doses, with potential repeat doses, compared to nCPAP alone. In addition, as with the initial phase 2a study, we also are assessing in these studies the performance of the CAG in the NICU and available physiological parameters for indications that aerosolized KL_4 surfactant is being delivered to the lungs. These studies are expected to be completed in the fourth quarter of 2015.

Also during the second quarter, Battelle and we completed the Stage 1 activities (design requirements) under our collaboration agreement and recently agreed upon project plan costs of up to approximately $11.85 million for Stage 2 (development activities) and Stage 3 (design verification and testing) activities. Under the collaboration agreement, we will be responsible for one half of the planned costs for Stage 2 and Stage 3, or up to approximately $6.0 million, with Battelle contributing a similar amount. We also agreed to amend our collaboration agreement to change the definition of "Milestone Date," or the anticipated date for completion of Stage 3 activities under the project plan, from May 31, 2016 to July 15, 2016. This modification also changes the definition of "Milestone Date" under the second warrant to purchase 500,000 shares of our common stock at an exercise price of $5.00 per share (the "Additional Warrant") issued to Battelle upon execution of the collaboration agreement. Under the terms of the Additional Warrant, it will become exercisable if and only if the Stage 3 activities are successfully completed by Battelle on or before the Milestone Date.

Currently, we are focusing our development efforts primarily on RDS through the development of AEROSURF. We believe that, with the knowledge that we gain from our efforts to develop AEROSURF for the treatment of RDS in premature infants with RDS, we may be able to leverage our proprietary aerosolized KL4 surfactant and novel drug delivery technologies potentially to address serious critical care respiratory conditions affecting pediatric and adult patient populations. While we remain focused on RDS, we have explored and plan in the future to explore potential opportunities to address such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI, where there are no currently approved therapies other than supportive respiratory care. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis. We believe that we have a potential opportunity to develop a broad pipeline of KL4 surfactant products and that investment in these indications could potentially yield products that may be effective to address significant unmet medical needs that also could represent significant market opportunities.

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 are incorporated herein and 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,	
	2015	**2014**	**2015**	**2014**
Selling, general and administrative expenses	$ 3,383	$ 4,446	$ 6,736	$ 8,869

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, 2015 decreased $1.1 million and $2.1 million, respectively, compared to the same periods in 2014 due to the April 2015 Restructuring and our efforts during the first quarter of 2015 to limit commercial and marketing expenses while we evaluated potential strategic alternatives for SURFAXIN.

Change in Fair Value of Common Stock Warrant Liability

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Change in fair value of common stock warrant liability	$ 469	$ 1,448	$ 438	$ 1,826

We account for common stock warrants in accordance with applicable accounting guidance provided in Accounting Standards Codification (ASC) Topic 815 *"Derivatives and Hedging – Contracts in Entity's Own Equity"* (ASC 815), 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 5, "Common Stock Warrant Liability," 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" in our 2014 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 presented.

Other Income and (Expense)

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Interest income	$ 1	$ 2	$ 2	$ 4
Interest expense	(1,260)	(1,131)	(2,468)	(2,224)
Other income / (expense)	(99)	–	133	–
Other income / (expense), net	$ (1,358)	$ (1,129)	$ (2,333)	$ (2,220)

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 primarily consists of interest expense associated with the Deerfield Loan (*see*, Note 6, "Deerfield Loan.")

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,	
	2015	2014	2015	2014
Cash interest expense	$ 654	$ 654	$ 1,301	$ 1,302
Non-cash amortization of debt discounts	594	470	1,149	909
Amortization of debt costs	5	5	10	10
Total interest expense	$ 1,253	$ 1,129	$ 2,460	$ 2,221

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.

For the three months ended June 30, 2015, other income / (expense) consists of a $0.1 million loss on disposal of assets associated with the April 2015 Restructuring and closure of the Totowa Facility. For the six months ended June 30, 2015, other income / (expense) consists of $0.2 million of proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits, partially offset by a $0.1 million loss on disposal of assets associated with the April 2015 Restructuring and closure of the Totowa Facility.

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, committed equity financing facilities, at-the-market equity programs, and capital equipment financings. We expect to fund our business operations in the future primarily through all or a combination of strategic alliances, public equity offerings, including under our ATM Program (*see*, "– At-the-Market Program (ATM Program)"), the potential exercise of outstanding warrants, and secured debt facilities.

As of June 30, 2015, we had cash and cash equivalents of $26.1 million and long-term debt of $30 million under our loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 6, "Deerfield Loan."). On July 22, 2015, we completed a public offering of common stock, warrants and pre-funded warrants, resulting in gross proceeds to us of approximately $40.25 million ($37.6 million net after deducting underwriting fees and estimated expenses, and including $5.0 million in non-cash consideration from Deerfield in satisfaction of future interest payments under the Deerfield Loan). *See*, "– Common Stock Offerings – July 2015 Registered Public Offering." Under our ATM Program, subject to market conditions, we may sell up to approximately $23 million of common stock at such times and in such amounts we deem appropriate, subject to a 3% commission. To secure additional capital when needed, we also will consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions. There can be no assurance, however, that we will be successful in securing additional capital when needed, if at all. Before any additional financings and taking into account the impact of certain July 2015 amendments to the Deerfield Loan and the Battelle collaboration agreement, discussed below, we anticipate that we will have sufficient cash available to support our AEROSURF® phase 2 clinical program, pay our debt service obligations and fund our operations through the first quarter of 2017.

In July 2015, we entered into two amendments to the Deerfield Loan agreement and related notes (Deerfield Notes), pursuant to which (i) we prepaid in cash $5.0 million of the outstanding principal amounts under the Deerfield Notes; (ii) the payment dates for the remaining principal installments due under the Deerfield Loan were amended to (x) eliminate the installment due in February 2017, and (y) adjust the amounts due on each of February 13, 2018 and February 13, 2019 to $12.5 million and $12.5 million, respectively; (iii) in our July 2015 public offering, in lieu of providing cash consideration, Deerfield accepted $5 million securities issued thereunder in prepayment of $5 million future interest obligations under the Deerfield Notes allocated in the manner provided in the amendment; and (iv) following application of the full $5 million interest prepayments described in clause (iii), the interest rate on any remaining interest due under the Deerfield Notes was adjusted from 8.75% to 8.25%.

Under our collaboration agreement with Battelle, we have completed Stage 1 (design requirements) of the three-stage project plan to develop our CAG device for potential use in our AEROSURF phase 3 clinical program and, if approved, initial commercial supply. In July 2015, we agreed on a planned cost of up to approximately $11.85 million to complete Stage 2 (development) and Stage 3 (design verification and testing) of the project plan, which under the collaboration agreement will be shared equally. Accordingly, we expect our 50% share of the planned cost for Stage 2 and Stage 3 to be up to approximately $6 million and that, following the completion of Stage 3 in mid-2016, we will be in a position to manufacture the CAG device and related componentry for use in the AEROSURF phase 3 clinical program. There can be no assurance that our collaboration will be successful or that we will timely complete the development work within the anticipated time, if ever, and for the anticipated cost contemplated under the collaboration project plan. Under the collaboration agreement, we also may defer payments due to Battelle for up to 12 months, provided that (i) any amounts deferred will bear interest from and after 90 days at a rate of 12% per annum, and (ii) the aggregate amounts deferred more than 30 days may not exceed at any time our available cash and cash equivalents. We currently have deferred $1.5 million and expect to defer aggregate payments of up to approximately $4.0 million at certain times throughout the term of the project.

For at least the next several years, we do not expect to generate any revenue from the sale of approved products. Thus, to secure the significant additional infusions of capital that we will need to execute our business strategy, advance our development programs, pay debt obligations and fund our operations, we will have to rely on non-sales sources of capital, including potentially: (i) strategic alliances and collaboration arrangements, which could provide development and commercial expertise to support the development and, if approved, commercial introduction of, our KL4 surfactant pipeline product candidates, beginning with AEROSURF, in 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. We believe that we will be better positioned to identify and enter into a significant strategic alliance for AEROSURF if we obtain encouraging results from the AEROSURF phase 2 clinical program; (ii) public and private equity offerings, including potentially pursuant to our ATM Program; (iii) secured debt arrangements to provide working capital and fund investment in capital assets; and (iv) the potential exercise of outstanding warrants (discussed below). In addition, we have in the past collaborated with research organizations and universities to assess potential application of our KL4 surfactant in studies funded in part through various U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical program and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological, and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. Although there can be no assurance, we expect that we may have opportunities in the future to participate in similar programs.

As of June 30, 2015, we had outstanding warrants to purchase approximately 13.2 million shares of our common stock at various prices, exercisable on different dates into 2024. This includes warrants to purchase up to 7.0 million shares that were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share (Deerfield Warrants). The Deerfield Warrants may be exercised for cash or through a net cashless exercise. 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 expire in February 2016 and 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-current exercise price of the warrants. The exercise price of these warrants was recently adjusted as a result of our July 2015 public offering and currently have an exercise price of $0.19 per share. If the holders determine in their discretion to exercise the February 2011 warrants prior to their expiration date in February 2016 (and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants), we potentially could receive up to approximately $0.9 million. In addition, in connection with the July 2015 public offering, we issued warrants to purchase up to approximately 67.1 million shares of common stock at an initial exercise price of $0.70 per share, and 42.0 million fully paid pre-funded warrants to purchase one share of common stock at an exercise price of $0.60 per share. The July 2015 warrants may be exercised at the election of the holder for cash or through a net cashless exercise. There can be no assurance that the price of our common stock will achieve a level greater than the exercise price of the Deerfield Warrants or the July 2015 warrants, that the holders 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. If any of 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. Moreover, if the holders of the February 2011 warrants choose to exercise their warrants at any time prior to the expiration date in February 2016, such exercises could be accompanied by increased selling activity in the Nasdaq market and the market value of our common stock could decline.

As of June 30, 2015, there were 250 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 136.0 million shares of common stock were available for issuance and not otherwise reserved. Of the 250 million shares of common stock that are presently authorized under our Amended and Restated Certificate of Incorporation, as amended, as of July 22, 2015, approximately 246.9 million shares of common stock are either issued and outstanding or reserved for issuance under our 2011 Equity Incentive Plans (2011 Plan), our 401(k) benefit plan, and upon exercise of outstanding warrants. If in the future we are unable to fund our capital requirements, we will not have sufficient cash flows and liquidity to fund our business operations and pay our debt service. In that event, we may be forced to further limit our development programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to secure additional capital, such transactions may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Moreover, if we fail in the future to make any required payment under our Deerfield Loan or fail to comply with any commitments contained in the loan documents, Deerfield would be able to declare us in default regarding that indebtedness, which could result in the acceleration of the payment obligations under all or a portion of our indebtedness. Since we have pledged substantially all of our assets to secure our obligations under the Deerfield Loan, a debt default would enable the lenders to foreclose on our assets securing the debt and could significantly diminish the market value and marketability of our common stock. Our financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

On June 29, 2015, we received a letter from The Nasdaq Stock Market indicating that for 30 consecutive business days our common stock had not maintained a minimum closing per share bid price of $1.00 ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). This notification had no immediate impact on the continued trading or listing of our common stock on Nasdaq. Under Nasdaq's Listing Rules, we have 180 calendar days from the date of the notification (the "Compliance Period"), or until December 28, 2015, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the closing bid price of our common stock must close above $1.00 for a minimum of 10 consecutive business days; thereafter, our common stock would continue to be eligible for listing on the Nasdaq Capital Market. If we are unable to achieve compliance with the Minimum Bid Price Requirement within 180 days, we may be eligible for a 180-day extension of the Compliance Period if we meet certain criteria set forth in the Nasdaq Listing Rules. If we fail to achieve compliance with the Minimum Bid Price Requirement within the applicable Compliance Period, the Nasdaq staff would issue a delisting notification and we would be subject to potential delisting, which if it occurred likely would further impair the liquidity and value of our common stock.

Cash Flows

As of June 30, 2015, we had cash and cash equivalents of $26.1 million compared to $44.7 million as of December 31, 2014. Cash outflows for the six months ended June 30, 2015 consisted of $18.3 million used for ongoing operating activities and $0.2 million for purchases of property and equipment.

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2015 and 2014 was $18.3 million and $20.3 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, 2015 represents capital expenditures of $0.5 million, partially offset by proceeds from sale of property and equipment of $0.3 million. Net cash used in investing activities for the six months ended June 30, 2014 represents capital expenditures of $0.9 million.

Financing Activities

Net cash used in financing activities for the six months ended June 30, 2015 was $41,000 and represents repayment of principal amounts due under an equipment loan. Net cash provided by financing activities for the six months ended June 30, 2014 is $0.4 million and represents proceeds from the exercise of warrants and stock options.

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, 2015, after reserves for outstanding unexercised warrants and amounts remaining under our ATM Program, approximately $219.3 million remained available under the 2014 Universal Shelf. The 2014 Universal Shelf will expire in June 2017.

July 2015 Registered Public Offering

On July 22, 2015, we completed a registered public offering of 25,083,332 Series A units and 42,000,000 Series B units each at a price per unit of $0.60, resulting in gross proceeds of $40.25 million ($37.6 million net after underwriting discount and estimated expenses), including the exercise in full by the underwriters of their option to purchase up to an additional 8,749,999 Series A units at a price per unit of $0.60 to cover over-allotments. The proceeds included $5.0 million in non-cash consideration from Deerfield in the form of a reduction in future interest payments due under the Deerfield Loan (*see*, Note 8, "Subsequent Events – Deerfield Loan Restructuring"). Each Series A unit consists of one share of common stock and a Series A warrant to purchase one share of common stock at an exercise price of $.70 per share. Each Series B unit consists of a fully paid pre-funded Series B warrant to purchase one share of common stock at an exercise price of $0.60 per share, and a Series B warrant to purchase one share of common stock at an exercise price of $.70 per share. The shares of common stock and warrants were immediately separable such that no units were issued. The warrants are exercisable immediately at the election of the holder for cash or through a net cashless exercise, provided that a holder may not exercise a warrant to the extent that after giving effect to such exercise, such holder would beneficially own in excess of 9.99% (or 4.99% as may be elected by such holder) of the shares of our common stock outstanding immediately after such exercise. All warrants will expire on the seventh anniversary of the issue date. The net proceeds will be used primarily (i) to advance the AEROSURF development program, and (ii) for general corporate purposes. The offering is being made pursuant to a preliminary prospectus supplement dated July 16, 2015 to the 2014 Universal Shelf.

In addition, in connection with the July 2015 public offering, we and each of our executive officers and directors entered into lock-up agreements pursuant to which we agreed not to dispose of or hedge any of our shares of common stock or securities convertible into or exercisable or exchangeable for common stock for 90 days after July 17, 2015, the date of the prospectus related to the offering, without first obtaining the written consent of the representative of the underwriters. In addition, we agreed with the underwriters that we will not sell shares of our common stock under our ATM Program for a period of 30 days from July 17, 2015 without the prior written consent of the representative of the underwriters. However, we may issue securities under exceptions specified in the underwriting agreement, including pursuant to our employee benefit and compensation plans, upon exercise of outstanding options, warrants and rights, under the Deerfield Loan agreement, and in connection with strategic alliances involving us. The 90-day "lock-up" period may be extended under certain circumstances specified in the lock-up and underwriting agreements.

As a result of the July 2015 public offering, our authorized shares available for issuance and not otherwise reserved is expected to be limited, at least until such time, if ever, that our stockholders approve an amendment to our Amended and Restated Certificate of Incorporation, as amended, that has the effect of increasing the authorized shares of common stock available for issuance and not reserved. Of the 250 million shares of common stock that are presently authorized under our Certificate of Incorporation, as of July 22, 2015, approximately 246.9 million shares of common stock are either issued and outstanding or reserved for issuance under our 2011 Equity Incentive Plan (2011 Plan), our 401(k) benefit plan, and upon exercise of outstanding warrants.

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 2014 Form 10-K. As of June 30, 2015, approximately $23 million 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 Senior Vice President and 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 Senior Vice President and 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 Senior Vice President and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in internal control

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, 2015 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 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 2014 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 2014 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 2014 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.

If we are unable to regain compliance with the Minimum Bid Price Requirement of The Nasdaq Capital Market prior to December 28, 2015, our stock price may decline and our common stock may be subject to delisting from Nasdaq. If our stock were no longer listed on NASDAQ, the liquidity of our securities would be impaired.

On June 29, 2015, we received a letter from The Nasdaq Stock Market indicating that for 30 consecutive business days our common stock had not maintained a minimum closing bid price of $1.00 per share as required by Nasdaq Listing Rule 5550(a)(2). Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar days following the date of the notification, or prior to December 28, 2015, the closing bid price of our stock is at or above $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the minimum bid price requirement and the common stock will continue to be eligible for listing on The Nasdaq Capital Market.

If we do not achieve compliance with the minimum bid price requirement by December 28, 2015, under Nasdaq Listing Rule 5810(c)(3)(A)(ii), if on December 28, 2015, we are in compliance with the market value requirement for continued listing of our common stock on The Nasdaq Capital Market as well as all other listing standards for initial listing of our common stock on the Nasdaq Capital Market (other than the minimum bid price requirement), and we provide written notice of our intention to cure the deficiency during a second compliance period, Nasdaq may grant us an additional compliance period through June 27, 2016.

If we receive a delisting determination from the Nasdaq staff, we may, at that time, request in writing that a Nasdaq Hearing Panel review the matter in a written or an oral hearing. Such a review, if granted, would stay delisting until a ruling from the Nasdaq Hearing Panel. After the Nasdaq Hearing Panel determination is final, we may then appeal the Hearing Panel decision to the Listing Council. If granted, such an appeal would not stay the Hearing Panel decision.

If our stock price does not exceed the minimum bid price of $1.00 within the periods set forth above, our common stock will be subject to delisting. If our common stock were no longer listed on The Nasdaq Capital Market or another national stock exchange, investors might only be able to trade in the over-the-counter markets. This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

If holders of our outstanding warrants exercise their warrants, 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; and to the extent that a number of holders exercise their warrants in the same time frame, including in anticipation of a warrant expiration date, such exercises could be accompanied by increased selling activity in the Nasdaq market, which would cause downward pressure on our stock price and the market value of our common stock could decline.

As of July 22, 2015, we had issued and outstanding approximately 122.3 million warrants to purchase shares of our common stock. Of these warrants, approximately 114 million are exercisable at a price per share of less than $1.00, including 42.0 million fully paid pre-funded warrants. If the market price of our common stock at any time is greater than the exercise price of our warrants and the holders of such warrants choose to exercise them, such exercises likely will be at a discount to the then-market value of our common stock and will have a dilutive effect on the value of our shares, and, to the extent that holders exercise their warrants in the same period, including in anticipation of a warrant expiration date, such exercises could be accompanied by increased selling activity in the Nasdaq market, which could cause downward pressure on our stock price and the market value of our common stock could decline. In particular, following our July 2015 public offering, the exercise price of the 4.6 million outstanding February 2011 warrants was adjusted to $0.19 per share in accordance with price-based anti-dilution provisions contained in the warrants. Since the exercise price of these warrants is currently at a discount to the current market value of our common stock, it is likely that the holders of these warrants would choose to exercise prior to the February 2016 expiration date.

We may need to seek and obtain stockholder approval of an increase in our authorized capital stock in order to pursue certain future transactions, including strategic alliances, collaboration agreements, and equity-based financings.

We currently have 250 million shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation, as amended. As of July 22, 2015, there were 246.9 million shares of common stock either issued and outstanding or reserved for future issuance under our 2011 Equity Incentive Plans, our 401(k) benefit plan, and upon exercise of outstanding warrants. If a potential future transaction requires us to issue shares of common stock, we likely will not have sufficient authorized capital to complete such transaction until we seek and obtain stockholder approval to increase our authorized capital stock. While we intend to seek approval of an increase in our authorized capital stock at or prior to the next annual meeting of our stockholders, we may not be successful in obtaining the necessary approval. Unless and until we obtain approval of an increase in our authorized capital stock, our ability to pursue strategic alliances, collaboration agreements, or other strategic transactions or equity-based financings that would entail the issuance of our shares may be restricted, which ultimately could have a material adverse effect on our business, financial condition and results of operations.

ITEM 5. OTHER INFORMATION

Effective as of August 4, 2015, we entered into an amendment (the “Amendment”) to the Collaboration Agreement with Battelle dated as of October 10, 2014 (the “Agreement”), pursuant to which we agreed to revise (i) the Project Plan Fixed Cost, as defined in the Agreement, to equal to an amount between $11.0 million and up to approximately $11.85 million, and (ii) the Discovery Labs Fixed Fee, as defined in the Agreement, to equal an amount between $5.5 million and up to $5.925 million, in each case, representing 50% of the revised Project Plan Fixed Cost. In addition, we agreed to revise the definition of Milestone Date from May 31, 2016 to July 15, 2016.

The foregoing summary is qualified in its entirety by reference to the text of the Amendment, which is attached as an exhibit to this Quarterly Report on Form 10-Q.

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 10, 2015

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

Date: August 10, 2015

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
4.1	Form of Series A Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.
4.2	Form of Pre-Funded Series B Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.
4.3	Form of Series B Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.
10.1	First Amendment dated as of July 9, 2015 to Facility Agreement dated as of February 13, 2013 between Discovery Laboratories, Inc. (Discovery) and affiliates of Deerfield Management Company, L.P. (Deerfield)	Incorporated by reference to Exhibit 4.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2015.
10.2	Second Amendment dated as of July 22, 2015 to Facility Agreement dated as of February 13, 2013 between Discovery Laboratories, Inc. (Discovery) and Deerfield	Incorporated by reference to Exhibit 4.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 24, 2015.
10.3	Amendment dated as of August 4, 2015 to Collaboration Agreement dated as of October 14, 2014 between Discovery and Battelle Memorial Institute.	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.

Exhibit No.	Description	Method of Filing
101.1	The following consolidated financial statements from the Discovery Laboratories, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, formatted in Extensive Business Reporting Language (“XBRL”): (i) Balance Sheets as of June 30, 2015 (unaudited) and December 31, 2014, (ii) Statements of Operations (unaudited) for the three months ended June 30, 2015 and June 30, 2014 (iii) Statements of Cash Flows (unaudited) for the six months ended June 30, 2015 and June 30, 2014, 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.

Exhibit 10.3

FIRST AMENDMENT TO COLLABORATION AGREEMENT

This First Amendment (“Amendment”) to Collaboration Agreement dated as of October 10, 2014 (the “Agreement”) is made and entered into as of August 4, 2015 (the "Amendment Date") by and between DISCOVERY LABORATORIES, INC., a corporation organized and existing under the laws of the state of Delaware having its principal place of business at 2600 Kelly Road, Suite 100, Warrington, PA 18976 USA ("Discovery Labs”), and BATTELLE MEMORIAL INSTITUTE, through its Corporate Operations, a corporation organized and existing under the laws of the state of Ohio having its principal place of business at 505 King Avenue, Columbus, Ohio 43201-2693, USA ("Battelle”).

RECITALS:

WHEREAS, in accordance with the terms of the Agreement, Battelle and Discovery Labs have recently concluded Stage I Work pursuant to the Project Plan and have agreed on the detailed Project Plan for implementation of the Stage 2 and Stage 3 activities contemplated by the Agreement, together with related costs, which shall be shared as provided in Section 3(B) of the Agreement.

NOW THEREFORE, IN CONSIDERATION OF THE COVENANTS AND PROMISES CONTAINED IN THIS AGREEMENT, THE PARTIES AGREE AS FOLLOWS WITH THE INTENT TO BE LEGALLY BOUND HEREBY:

1. Capitalized terms used in this Amendment and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Agreement.

2. In accordance with Section 3(B)(i) of the Agreement, the Project Plan Fixed Cost is revised to equal to an amount between (a) Eleven Million Dollars ($11.0M) and (b) up to Eleven Million, Eight Hundred Fifty Thousand Dollars ($11.85M); and, accordingly, the Discovery Labs Fixed Fee as of the Amendment Date remains 50% of the Project Plan Fixed Cost, or an amount between (a) Five Million, Five Hundred Thousand Dollars ($5.5M) and (b) up to (b) Five Million, Nine Hundred Twenty-Five Thousand Dollars ($5.925M) (in each case, representing 50% of the revised Project Plan Fixed Cost).

3. The reference to "May 31, 2016" in the defined term "Milestone Date" set forth in the first sentence of Section 3(E)(ii) of the Agreement is revised to "July 15, 2016."

Except as amended herein, the remaining terms and conditions of the Agreement shall remain in full force and effect. This Amendment confirms an agreement between the Parties with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and the mutual promises made in connection therewith. The provisions of Section 9(H) - (K) of the Agreement shall apply to this Amendment *mutatis mutandi*.

[Signatures appear on the next page]

In Witness Whereof, the Parties have duly executed this Amendment as of the Amendment Date.

Battelle Memorial Institute Corporate Operations	Discovery Laboratories, Inc.
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____

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 10, 2015

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

Exhibit 31.2

CERTIFICATIONS

I, John A. 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 10, 2015

/s/John A. Tattory
John A. 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, 2015 (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 10, 2015

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

/s/ John A. Tattory
John A. 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.