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 September 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 November 2, 2015, there were outstanding 112,064,773 shares of the registrant's common stock, par value $0.001 per share.

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PART I - FINANCIAL INFORMATION

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements 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 AEROSURF® for respiratory distress syndrome (RDS) in premature infants, and potentially other aerosolized KL4 surfactant products that we may develop in the future; 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, collaborative arrangements and other potential strategic transactions 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 AEROSURF, our combination drug/device product candidate based on our lyophilized KL4 surfactant and our novel capillary aerosol generator (CAG), and potential KL4 surfactant drug product, device and combination drug/device product candidates that we may seek to develop in the future;

- the risk that our AEROSURF phase 2 clinical program may be interrupted, delayed, or fail, which will harm our business prospects, that we may experience slower-than-anticipated initiation of our participating clinical sites, including in locations outside the U.S., and slower-than-anticipated enrollment in our ongoing AEROSURF phase 2 clinical trials;

- 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, to advance our development activities, we will require, and may be unable to secure, significant additional capital (whether from strategic transactions, 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;

- the risk that we may be unable to enter into strategic alliances, collaboration agreements or other strategic transactions 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;

- The risk that, until such time as our stockholders approve the filing of an amendment to our Amended and Restated Certificate of Incorporation, as amended, to increase the number of shares of common stock authorized thereunder, our ability to fund our operations through strategic and financing transactions involving the issuance of common stock will be severely limited;

- The risk that unfavorable credit and financial markets may adversely affect our ability to fund our activities through equity financings, including our at-the-market equity sales program (ATM Program), and that our ATM Program may expire in February 2016 unutilized;

- risks associated with our outstanding warrants, including that 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; that holders of our warrants, including the February 2011 warrants that expire in February 2016 and have an exercise price of $0.19 per share, may choose in their discretion to exercise their warrants, whether in response to increases in the market value of our common stock or in anticipation of an impending expiration date, and that such exercises could be accompanied by increased selling activity in the Nasdaq market, resulting in downward pressure on the value of our common stock. Moreover, to the extent that, and for so long as, such selling activity occurs, it could have the effect of limiting the upside potential value of our common stock.

- risks relating to the transfer of our manufacturing technology at our 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 aerosol device products and component parts based on our CAG technology to support our 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.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 46,308	$ 44,711
Inventory, net	–	27
Prepaid interest, current portion	1,986	–
Prepaid expenses and other current assets	433	821
Total current assets	48,727	45,559
Property and equipment, net	1,186	1,637
Restricted cash	225	225
Prepaid interest, non-current portion	2,594	–
Other assets	–	78
Total assets	$ 52,732	$ 47,499
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,457	$ 350
Accrued expenses	6,832	6,116
Deferred revenue	–	43
Common stock warrant liability	497	1,258
Equipment loans, current portion	–	62
Total current liabilities	9,786	7,829
Long-term Debt:		
Long-term debt, gross	25,000	30,000
Discount on long-term debt	–	(9,698)
Long-term debt, net	25,000	20,302
Other liabilities	56	169
Total liabilities	34,842	28,300
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 250,000,000 shares authorized; 112,085,665 and 85,607,806 shares issued at September 30, 2015 and December 31, 2014, respectively; 112,064,773 and 85,586,914 shares outstanding at September 30, 2015 and December 31, 2014, respectively	112	86
Additional paid-in capital	589,901	546,175
Accumulated deficit	(569,069)	(524,008)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total stockholders' equity	17,890	19,199
Total liabilities & stockholders' equity	$ 52,732	$ 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Product sales	$ –	$ 106	$ 7	$ 176
Grant revenue	66	421	325	1,475
	66	527	332	1,651
Expenses:				
Cost of product sales	–	257	929	1,769
Research and development	6,452	6,471	20,663	18,919
Selling, general and administrative	2,057	4,126	8,793	12,995
	8,509	10,854	30,385	33,683
Operating loss	(8,443)	(10,327)	(30,053)	(32,032)
Change in fair value of common stock warrant liability	139	173	577	1,999
Other income / (expense):				
Loss on debt extinguishment	(11,758)	–	(11,758)	–
Interest and other income	1	2	235	6
Interest and other expense	(1,495)	(1,172)	(4,062)	(3,396)
Other income / (expense), net	(13,252)	(1,170)	(15,585)	(3,390)
Net loss	$ (21,556)	$ (11,324)	$ (45,061)	$ (33,423)
Net loss per common share				
Basic	$ (0.20)	$ (0.13)	$ (0.49)	$ (0.39)
Diluted	$ (0.20)	$ (0.13)	$ (0.49)	$ (0.41)
Weighted average number of common shares outstanding				
Basic	105,696	85,209	92,420	85,001
Diluted	105,696	85,209	92,420	86,121

See notes to consolidated financial statements.

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

(in thousands)

	Nine Months Ended September 30, 2015	2014
Cash flows from operating activities:		
Net loss	$ (45,061)	$ (33,423)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	626	577
Change in provision for excess inventory	(174)	1,596
Stock-based compensation and 401(k) Plan employer match	1,750	3,053
Fair value adjustment of common stock warrants	(577)	(1,999)
Amortization of discount on long-term debt	1,287	1,414
Loss on debt extinguishment	11,758	–
Debt discount write-off	707	–
Loss on sale of equipment	84	–
Changes in:		
Inventory	201	(2,319)
Accounts receivable	–	45
Prepaid interest, current portion	420	–
Prepaid expenses and other current assets	388	420
Accounts payable	2,107	(30)
Accrued expenses	716	19
Deferred revenue	(43)	(44)
Other assets	66	–
Other liabilities	(113)	(396)
Net cash used in operating activities	(25,858)	(31,087)
Cash flows from investing activities:		
Purchase of property and equipment	(508)	(679)
Proceeds from sale of property and equipment	260	–
Net cash used in investing activities	(248)	(679)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	32,629	–
Proceeds from exercise of common stock options	–	31
Proceeds from exercise of common stock warrants	136	426
Principal payments on long-term debt	(5,000)	–
Repayment of equipment loans	(62)	(59)
Net cash provided by financing activities	27,703	398
Net increase (decrease) in cash and cash equivalents	1,597	(31,368)
Cash and cash equivalents – beginning of period	44,711	86,283
Cash and cash equivalents – end of period	$ 46,308	$ 54,915
Supplementary disclosure of cash flows information:		
Interest paid	$ 1,453	$ 1,968

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). In April 2015, we voluntarily ceased the commercialization of SURFAXIN, a liquid instillate, in order to 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 aerosolized KL4 surfactant to premature infants supported by nCPAP alone, 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 three escalating inhaled doses (15, 30 and 45 minutes) 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 delivered into the lung of premature infants, and (2) acceptable performance of the novel CAG technology in the NICU. The key objectives of this trial were met.

In October 2015, we announced that we have completed enrollment in an AEROSURF phase 2a clinical 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) doses compared to nCPAP alone. We expect to release top line results of this study in mid-November. We also have begun enrollment for a phase 2a clinical 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 two escalating (30 and 45 minutes) doses, with potential repeat doses, compared to nCPAP alone. We anticipate releasing top-line results of this study in the first quarter of 2016. As with the initial phase 2a study, in both follow-on studies we are assessing performance of the CAG in the NICU and available physiological data for indications that aerosolized KL4 surfactant is being delivered to the lungs.

We are also preparing for an AEROSURF phase 2b clinical trial, with enrollment expected to begin in the fourth quarter of 2015 and 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, or magnitude of benefit. This clinical trial is expected to enroll up to 250 premature infants 26 to 32 week gestational age (beginning with infants 29 to 32 week gestational age, followed by infants 26 to 28 week gestational age) who are receiving nCPAP for RDS and will assess aerosolized KL_4 surfactant administered in two escalating doses, compared to nCPAP alone. We expect to conduct this trial with up to approximately 50 clinical sites within and outside the United States (U.S.).

With the knowledge that we gain from developing AEROSURF for the treatment of RDS in premature infants, we believe that we may be able to develop our proprietary aerosolized KL_4 surfactant and 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, primarily in collaborations with research organizations and universities to assess potential application of our KL_4 surfactant in studies funded in part through various U.S. Government-sponsored programs, including grants in support of our AEROSURF clinical program and biodefense-related initiatives that encourage private sector development of medical countermeasures against chemical, biological, radiological, nuclear terrorism threat agents and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. We expect that we may have opportunities in the future to participate in similar programs. If funding is available, we would likely seek 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, if funding is available, we would consider 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 our proprietary aerosolized KL_4 surfactant and drug delivery technologies potentially could support a pipeline of KL_4 surfactant products that could address significant unmet medical needs and represent significant market opportunities. There can be no assurance, however, that we will be successful in securing the funding required to continue our exploratory development work, through grant awards, investigator-initiated programs or otherwise, and even if we are successful in continuing our efforts, that we will be successful with our efforts.

Note 2 – Liquidity Risks and Management's Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, as well as efforts through April 2015 to commercialize SURFAXIN, including marketing, commercial 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, collaboration agreements and other strategic transactions, public and private equity offerings, the potential exercise of outstanding warrants and, in the future, potential secured debt facilities.

As of September 30, 2015, we had cash and cash equivalents of $46.3 million and long-term debt of $25 million under our loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 7, "Deerfield Loan"). In July 2015, we completed a registered public offering of approximately 25.1 million Series A units and 42.0 million 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 expenses). The proceeds included $5.0 million in non-cash consideration from Deerfield (discussed below). In July 2015, we amended our Deerfield Loan agreement and related notes (Deerfield Notes) to (i) prepay in cash $5.0 million of the outstanding principal amounts under the Deerfield Notes; (ii) eliminate the principal installment due in February 2017, (iii) adjust the amounts due on each of February 13, 2018 and February 13, 2019 to $12.5 million and $12.5 million, respectively, (iv) prepay $5 million future interest obligations under the Deerfield Notes, which payment was made in the form of $5 million of securities issued in connection with the July 2015 public offering, and (v) reduce the interest rate for any remaining interest due under the Deerfield Notes from 8.75% to 8.25%. Before any additional financing activities, we anticipate that we will have sufficient cash available to support our AEROSURF phase 2 clinical program, pay our current debt service and fund our operations through the first quarter of 2017.

Under our collaboration agreement with Battelle, we 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 project plan cost of up to $11.85 million to complete Stage 2 (development) and Stage 3 (design verification and testing) of the project plan, which will be shared equally. Accordingly, we expect that our 50% share of the project plan cost for Stage 2 and Stage 3 will be up to approximately $6 million and, following the completion of Stage 3 in mid-2016, we expect to 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 at no more than the anticipated shared cost to us of up to approximately $6 million. 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 $2.4 million and expect to defer aggregate payments of up to approximately $4.0 million at certain times throughout the term of the project.

We do not expect to generate any revenue from the sale of approved products for at least the next several years. To secure the significant additional infusions of capital that we will need to execute our business strategy, advance our AEROSURF development program, pay our obligations and fund our operations, we will have to rely on other sources of capital. We have historically raised additional capital through public and private equity offerings as well as strategic transactions. However, as of October 30, 2015, we have only approximately 3.1 million authorized shares of common stock available for potential equity offerings. Based on the closing market price per share of our common stock on October 30, 2015 ($0.31), we would be limited to raising a maximum of approximately $1.0 million. To raise additional capital through equity offerings, we would be required first to seek stockholder approval to increase the authorized shares of common stock provided under our Amended and Restated Certificate of Incorporation, as amended (Certificate of Incorporation), a process that could require a special meeting of stockholders, be time-consuming and expensive and could prevent or impair our efforts to efficiently raise capital when needed, if at all. In addition, the large number of outstanding warrants (discussed below), including the February 2011 warrants that expire in February 2016 and are currently exercisable at a price per share of $0.19, potentially could depress the market value of our common stock, even if we otherwise are successful, and potentially make it more difficult to raise capital through equity offerings, if at all, on acceptable terms. To secure potentially non-dilutive sources of capital, we have in the past and plan in the future to consider strategic transactions, including without limitation potential strategic alliances and collaboration arrangements that could provide development and commercial expertise to support the development and, if approved, commercial introduction, of AEROSURF and other future KL4 surfactant product candidates. 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 have been engaged in ongoing communications with several potential strategic counterparties, including in the first quarter of 2015 with respect to SURFAXIN. Such entities have expressed interest in AEROSURF, and our KL4 surfactant and drug delivery technologies. We believe that we will be better positioned to identify and enter into alliances and other strategic transactions focused on AEROSURF if we obtain encouraging results from our AEROSURF phase 2 clinical program. In addition, we could also consider other non-dilutive financing transactions, including debt arrangements and secured financing transactions to fund investment in capital assets. There can be no assurance, however, that we will be successful in securing the capital we will require, whether through public or private equity offerings, strategic alliances, collaboration agreements or other strategic transactions, or through debt arrangements or the financing of capital assets. Failure to secure the necessary capital could have a material adverse effect on our business, financial condition and results of operations.

As of September 30, 2015, we had outstanding warrants to purchase approximately 121.6 million shares of our common stock at various prices, exercisable on different dates into 2024. This includes:

- warrants issued in July 2015, including (i) warrants to purchase up to approximately 67.1 million shares of common stock at an initial exercise price of $0.70 per share, and (ii) pre-funded warrants to purchase up to 42.0 million shares of common stock at an exercise price of $0.60 per share, of which the entire purchase price was pre-paid upon issuance. The July 2015 warrants are exercisable in whole or in part at any time for cash or through a cashless exercise through July 22, 2022. The July 2015 pre-funded warrants are fully paid and may be exercised at any time through July 22, 2022;

- warrants issued in February 2011 to purchase up to approximately 3.8 million shares of common that contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-current exercise price of the warrants. The exercise price of these warrants was adjusted in connection with our July 2015 public offering to $0.19 per share. The February 2011 warrants expire on February 22, 2016; and

- warrants issued to Deerfield in connection with the Deerfield Loan to purchase up to 7.0 million shares of common stock at an exercise price of $2.81 per share (Deerfield Warrants). The Deerfield Warrants may be exercised for cash or through a cashless exercise at any time through February 13, 2020. In lieu of paying cash upon exercise, the holders of the Deerfield Warrants 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.

There can be no assurance that the price of our common stock will achieve a level greater than the exercise price of the July 2015 warrants or the Deerfield 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. Upon exercise of the July 2015 pre-funded warrants, which were fully-paid at issuance, we would issue the shares to the holders and receive no additional proceeds. If the holders of the February 2011 warrants choose to exercise their warrants at any time prior to the expiration date in February 2016, we potentially could receive proceeds of up to approximately $0.7 million; however, such exercises could be accompanied by increased selling activity in the Nasdaq market and the market value of our common stock could decline.

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. *See*, Note 1, "The Company and Description of Business." Although there can be no assurance, we expect that we may have opportunities in the future to participate in similar programs.

If in the future we are unable to fund our capital requirements, we likely will not have sufficient cash flow and liquidity to fund our business operations and pay our debt service, which could have a material adverse effect on our business and operations. In that event, we may be forced to severely 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.

As of September 30, 2015, there were 250 million shares of common stock authorized under our Certificate of Incorporation and approximately 3.1 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 Certificate of Incorporation, 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, our ATM Program and upon exercise of outstanding warrants.

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). 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 do not achieve compliance with the Minimum Bid Price Requirement prior to December 28, 2015, 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 nine months ended September 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 manufacturing facility in Totowa, NJ (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 total 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 and $0.6 million of the severance and retention benefits during the second and third quarters of 2015, respectively. The remaining $0.5 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 September 30, 2015 and 2014, the number of shares of common stock potentially issuable upon the exercise of stock options and warrants was 129.2 million and 20.8 million shares, respectively. As of September 30, 2015 and 2014, 129.2 million and 16.2 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 September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Numerator:				
Net loss as reported	$ (21,556)	$ (11,324)	$ (45,061)	$ (33,423)
Less: income from change in fair value of warrant liability	(139)	–	(577)	(1,993)
Numerator for diluted net loss per common share	$ (21,695)	$ (11,324)	$ (45,638)	$ (35,416)
Denominator:				
Basic weighted average common shares Outstanding	105,696	85,209	92,420	85,001
Dilutive common shares from assumed warrant exercises	–	–	–	1,120
Diluted weighted average common shares outstanding	105,696	85,209	92,420	86,121

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

Note 4 – Stockholders' Equity

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 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 7 – 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.

In connection with the July 2015 registered public offering, the exercise price of warrants that we issued in a February 2011 was adjusted in accordance with anti-dilution provisions in the warrants, which generally may apply 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, and include a method to value the share component of a unit offering. As a result, the exercise price of these warrants was reduced from $1.50 to $0.19 per share There are currently outstanding 3.8 million February 2011 warrants, which will expire on February 22, 2016.

Note 5 – Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

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

Fair Value on a Recurring Basis

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

	Fair Value	Fair value measurement using		
	September 30, 2015	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 46,308	$ 46,308	$ –	$ –
Certificate of deposit	225	225	–	–
Total Assets	$ 46,533	$ 46,533	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 497	$ –	$ –	$ 497

	Fair Value	Fair value measurement using		
	December 31, 2014	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 tables below summarize the activity of Level 3 inputs measured on a recurring basis for the nine months ended September 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
Exercise of warrants	(184)
Change in fair value of common stock warrant liability	(577)
Balance at September 30, 2015	$ 497

(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	(377)
Change in fair value of common stock warrant liability	(1,999)
Balance at September 30, 2014	$ 3,049

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	September 30, 2015	December 31, 2014
Historical volatility	99%	55% – 84%
Expected term (in years)	0.4	0.1 – 1.1
Risk-free interest rate	0.05%	0.03% – 0.31%

Fair Value of Long-Term Debt

At September 30, 2015, the estimated fair value of the Deerfield Loan (*see*, Note 7, "Deerfield Loan") approximated the carrying value of $25.0 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 6 – Common Stock Warrant Liability

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

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 September 30, 2015, there were 3.8 million warrant shares potentially issuable upon exercise of these warrants, with a fair value of $0.5 million. These warrants contain anti-dilution provisions that in certain circumstances 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. As of September 30, 2015, the exercise price of these warrants is $0.19 per share. Changes in the estimated fair value of warrants classified as derivative liabilities are reported in the accompanying Consolidated Statement of Operations as the "Change in fair value of common stock warrants."

During the three months ended September 30, 2015 and 2014, holders of the February 2011 warrants exercised warrants to purchase 716,704 and 2,500 shares of common stock, respectively, for total proceeds of $136,000 and $3,000, respectively. During the nine months ended September 30, 2015 and 2014, holders of the February 2011 warrants exercised warrants to purchase 716,704 and 284,850 shares of common stock, respectively, for total proceeds of $136,000 and $426,000 , respectively.

Note 7 – Deerfield Loan

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

(in thousands)	**September 30, 2015**	**December 31, 2014**
Note payable	$ 25,000	$ 30,000
Unamortized discount	–	(9,698)
Long-term debt, net of discount	$ 25,000	$ 20,302

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, (i) upon execution, we prepaid in cash $2.5 million of the principal amounts outstanding under the Deerfield Loan, (ii) on July 22, 2015, we prepaid an additional $2.5 million of the principal amounts then outstanding upon the occurrence of the July 2015 public offering, (iii) the principal installment originally due in February 2017 was eliminated and (iv) the installments due in each of February 2018 and 2019 were adjusted to $12.5 million and $12.5 million, respectively. We also paid Deerfield's expenses (including reasonable counsel fees and expenses of up to $15,000) incurred in connection with the amendment. Under the Deerfield Loan agreement, 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.

On July 22, 2015, we entered into a second amendment to our Deerfield Loan agreement and Deerfield Notes. Under the terms of the second amendment, (a) upon the closing of the July 2015 public offering on July 22, 2015, we prepaid in cash $2.5 million of the principal amounts then outstanding under the Deerfield Loan, as contemplated by the first amendment, and (b) Deerfield purchased and accepted $5 million Series A and Series B units offered in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes. In addition, (i) we paid in cash when due on September 30, 2015, all accrued and unpaid interest due under the Deerfield Notes for the period from June 30, 2015 to July 22, 2015 at the existing rate of 8.75%; (ii) Deerfield has agreed to apply the $5 million prepayment of interest accruing from and after July 23, 2015, as and when such payments are due and payable, as follows; first, to interest accruing on the $12.5 million principal installment due on February 13, 2019, and second, to interest accruing on the $12.5 million principal installment due on February 13, 2018, until fully allocated, which is scheduled to occur at the end of the second quarter of 2016; (iii) after the full allocation of the $5 million interest prepayment, any remaining interest due on the principal amount of the Deerfield Notes will thereafter accrue at a rate of 8.25% per annum; and (iv) no credit shall be given with respect to prepaid interest on principal under the Deerfield Notes that is prepaid, in whole or in part, except for a prepayment at our election or a prepayment required under the Deerfield Loan agreement in connection with a major transaction (as defined in the Deerfield Loan agreement) that qualifies as a "Qualified Major Transaction." A "Qualified Major Transaction" means a change of control transaction (as defined in the Deerfield Warrants), in which (i) we are not the surviving entity and (ii) our common stock valuation (as defined in the Deerfield Warrants) immediately prior to the change of control transaction equals or exceeds $100 million. In addition, we have paid Deerfield's expenses (including reasonable counsel fees and expenses) incurred in connection with the second amendment.

The restructuring of the Deerfield Loan qualifies as an extinguishment of debt in accordance with ASC Topic 470, *Debt - Modifications and Extinguishments*, and as a result, we have incurred an $11.8 million non-cash loss on debt extinguishment consisting primarily of (1) the $7.7 million difference between the reacquisition price of the Deerfield Loan and the net carrying amount of the extinguished Deerfield Loan, and (2) the $4.1 million in fair value of the Series A and Series B warrants issued to Deerfield as part of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes.

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cash interest expense	$ 150	$ 662	$ 1,451	$ 1,963
Non-cash amortization of debt discounts	138	504	1,287	1,414
Debt discount write-off	707	–	707	–
Amortization of prepaid interest expense	420	–	420	–
Amortization of debt costs	2	5	12	15
Write-off of debt costs	66	–	66	–
Total interest expense	$ 1,483	$ 1,171	$ 3,943	$ 3,392

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 Deerfield Warrants. Debt discount write-off represents the proportional write-off of unamortized debt discount at the time of a $2.5 million prepayment of principal amount outstanding under the Deerfield Loan. Amortization of prepaid interest expense represents non-cash amortization of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan, and the write-off of debt costs represents the write-off of the remaining costs at the time of the debt restructuring.

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 per share of $2.81 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 8 – Stock Options and Stock-Based Employee Compensation

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

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula based on the following weighted average assumptions:

	September 30, 2015	September 30, 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 September 30, 2015	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
Research & development	$ 192	$ 313	$ 551	$ 860
Selling, general & administrative	226	544	801	1,482
Total	$ 418	$ 857	$ 1,352	$ 2,342

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). In April 2015, we voluntarily ceased the commercialization of SURFAXIN, a liquid instillate, in order to 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 aerosolized KL4 surfactant to premature infants supported by nCPAP alone, 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. *See*, "–Business and Pipeline Program Updates."

With the knowledge that we gain from developing AEROSURF for the treatment of RDS in premature infants, we believe that we may be able to develop our proprietary aerosolized KL4 surfactant and 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, primarily in collaborations with research organizations and universities to assess potential application of our KL4 surfactant in studies funded in part through various U.S. Government-sponsored programs, including grants in support of our AEROSURF clinical program and biodefense-related initiatives that encourage private sector development of medical countermeasures against chemical, biological, radiological, nuclear terrorism threat agents and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. We expect that we may have opportunities in the future to participate in similar programs. If funding is available, we would likely seek 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, if funding is available, we would consider 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 our proprietary aerosolized KL4 surfactant and drug delivery technologies potentially could support a pipeline of KL4 surfactant products that could address significant unmet medical needs and represent significant market opportunities. There can be no assurance, however, that we will be successful in securing the funding required to continue our exploratory development work, through grant awards, investigator-initiated programs or otherwise, and even if we are successful in continuing our efforts, that we will be successful with our efforts.

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:

- 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 three escalating inhaled doses (15, 30 and 45 minutes) 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 delivered into the lung of premature infants, and (2) acceptable performance of the novel CAG technology in the NICU. The key objectives of this trial were met.

- In October 2015, we announced that we have completed enrollment in an AEROSURF phase 2a clinical 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) doses compared to nCPAP alone. We expect to release top line results of this study in mid-November. As with the initial clinical trial, we also assessed performance of the CAG in the NICU and available physiological data for indications that aerosolized KL4 surfactant is being delivered to the lungs. We expect to release top line results of this study in mid-November.

- We have begun enrollment for a phase 2a clinical 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 two escalating (30 and 45 minutes) doses, with potential repeat doses, compared to nCPAP alone. As with the initial phase 2a studies, we plan to continue assessing performance of the CAG in the NICU and available physiological data for indications that aerosolized KL4 surfactant is being delivered to the lungs of premature infants. We anticipate releasing top-line results of this study in the first quarter of 2016.

- We are also preparing for an AEROSURF phase 2b clinical trial, with enrollment expected to begin in the fourth quarter of 2015 and 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, or magnitude of benefit. This clinical trial is expected to enroll up to 250 premature infants 26 to 32 week gestational age (beginning with infants 29 to 32 week gestational age, followed by infants 26 to 28 week gestational age) who are receiving nCPAP for RDS and will assess aerosolized KL4 surfactant administered in two escalating doses, compared to nCPAP alone. We expect to conduct this trial with up to approximately 50 clinical sites within and outside the United States (U.S.).

- We continue our work with Battelle Memorial Institute (Battelle) (i) for the continued development and manufacture of our CAG devices and disposable AEROSURF dose packs (ADPs) to support the remainder of our phase 2 clinical program, and (ii) to advance our October 2014 collaboration to further develop our CAG device for use in our planned phase 3 clinical program and, if AEROSURF is approved, initial commercial activities. 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 project plan cost of up to $11.85 million to complete Stage 2 (development) and Stage 3 (design verification and testing) of the project plan. We also agreed to amend our collaboration agreement to change the definition of “Milestone Date” (the target date for completion of 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 our work with Patheon Manufacturing Services LLC (Patheon, formerly DSM Pharmaceuticals, Inc.) to complete a technology transfer of our lyophilized KL4 surfactant manufacturing process and complete early manufacturing development activities for our lyophilized KL4 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 KL4 surfactant for our potential AEROSURF phase 3 clinical program, as well as other potential pipeline development programs. In addition, 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, our first KL4 surfactant product and the first synthetic, peptide-containing surfactant approved by the FDA, potentially to support our efforts and offset the rate of cash outflows that we were experiencing for manufacturing, operations, medical and commercial activities for SURFAXIN, but concluded that none could be accomplished on acceptable terms and within an acceptable time. In April 2015, we implemented a restructuring plan (April 2015 Restructuring) 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 and our AEROSURF clinical program. We reduced our workforce by approximately 50 percent and ceased manufacturing activities at our manufacturing operations in Totowa, NJ (Totowa Facility), which we closed upon the expiration of our lease on June 30, 2015. In addition, due to these actions, we are no longer considering in the near term a potential development plan to gain approval for SURFAXIN LS™, our lyophilized KL4 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 September 30, 2015 and 2014 was $21.6 million (or $0.20 basic net loss per share) and $11.3 million (or $0.13 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 $0.1 million and $0.2 million for 2015 and 2014, respectively; (ii) for 2015, an $11.8 million non-cash loss on debt extinguishment; and (iii) interest expense of $1.5 million (including a $0.7 million non-cash write-off of previously capitalized debt discount costs upon prepayment of $2.5 million of principal amount) and $1.2 million for 2015 and 2014, respectively, associated with the Deerfield Loan.

The net loss for the nine months ended September 30, 2015 and 2014 was $45.1 million (or $0.49 basic net loss per share) and $33.4 million (or $0.39 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 $0.6 million and $2.0 million for 2015 and 2014, respectively; (ii) for 2015, an $11.8 million non-cash loss on debt extinguishment; and (iii) interest expense of $3.9 million (including a $0.7 million non-cash write-off of previously capitalized debt discount costs) and $3.4 million for 2015 and 2014, respectively, associated with the Deerfield Loan.

The operating loss for the three months ended September 30, 2015 and 2014 was $8.4 million and $10.3 million, respectively. The decrease in operating loss from 2014 to 2015 was due to a $2.3 million decrease in operating expenses partially offset by a $0.4 million decrease in grant revenues.

The operating loss for the nine months ended September 30, 2015 and 2014 was $30.1 million and $32.0 million, respectively. The decrease in operating loss from 2014 to 2015 was due to a $3.3 million decrease in operating expenses partially offset by a $1.2 million decrease in grant revenues and a $0.2 million decrease in product sales.

Grant Revenue

We recognized grant revenue of $0.1 million and $0.4 million for the three months ended September 30, 2015 and 2014, respectively, and $0.3 million and $1.5 million for the nine months ended September 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 provided support for the initial AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age with RDS. 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. For 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 received the balance of that initial award. During the fourth quarter, we anticipate receiving amounts 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 nine months ended September 30, 2015 and 2014 are as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Product development and manufacturing	$ 2,872	$ 3,806	$ 11,071	$ 10,728
Medical and regulatory operations	1,711	2,001	5,137	5,848
Direct preclinical and clinical programs	1,869	664	4,455	2,343
Total research & development expenses	$ 6,452	$ 6,471	$ 20,663	$ 18,919

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 September 30, 2015 and 2014, respectively, and of $0.9 million and $1.4 million for the nine months ended September 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 September 30, 2015 decreased $0.9 million compared to the same period in 2014, due to the closure of the Totowa Facility in June 2015 (expenses related to operation of the Totowa Facility during the same period in 2014 were $1.6 million), partially offset by an investment in 2015 of $0.7 million under our collaboration agreement with Battelle to further develop our CAG device for use in our planned phase 3 clinical program for AEROSURF and, if approved, initial commercial activities.

Product development and manufacturing expenses for the nine months ended September 30, 2015 increased $0.3 million compared to the same period in 2014, due to an investment of $2.1 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, partially offset by a decrease of $1.9 million in manufacturing costs due to the closure of the Totowa Facility in June 2015.

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 September 30, 2015 decreased $0.3 million compared to the same period in 2014 due to a $0.3 million decrease in medical affairs and regulatory activities resulting from the April 2015 Restructuring.

Medical and regulatory operations expenses for the nine months ended September 30, 2015 decreased $0.7 million compared to the same period in 2014 due to a $1.1 million decrease in medical affairs activities resulting from 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 $0.5 million increase related to enhancing 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 for the three months ended September 30, 2015 increased $1.2 million compared to the same period in 2014 due to an 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.

Direct preclinical and clinical programs expenses for the nine months ended September 30, 2015 increased $2.1 million compared to the same period in 2014 due to a $2.5 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) development of our aerosol delivery technologies, 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 project costs to further develop our CAG device for use in our planned AEROSURF phase 3 clinical program and, if approved, initial commercial activities (we are responsible for changes to the scope of the plan and Battelle is responsible for any cost-overruns); and (iii) lyophilized KL_4 surfactant, which we are developing initially for use in our AEROSURF development program.

To support our ongoing AEROSURF phase 2 clinical program 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 supply, 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, conduct our phase 2b clinical trial and execute the later stages of the planned AEROSURF clinical development program.

For a summary of our AEROSURF clinical activities and other updates since the filing of our 2014 Form 10-K, *see*, "Overview – Business and Pipeline Program Updates," and our Current Report on Form 8-K that we filed with the SEC on May 14, 2015. The AEROSURF initial phase 2a clinical trial was supported, in part, by a $1.9 million Phase II award 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) under award number 4R44HL107000-02. The content of this quarterly report is solely the responsibility of the Company and does not necessarily represent the official views of the National Institutes of Health.

Also during the second quarter, Battelle and we completed the Stage 1 activities (design requirements) under our collaboration agreement and 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. *See*, "– Overview – Business and Pipeline Program Updates." 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.

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Selling, general and administrative expenses	$ 2,057	$ 4,126	$ 8,793	$ 12,995

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 nine months ended September 30, 2015 decreased $2.1 million and $4.2 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Change in fair value of common stock warrant liability	$ 139	$ 173	$ 577	$ 1,999

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 trinomial pricing model, based 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Loss on debt extinguishment	$ (11,758)	$ –	$ (11,758)	$ –
Interest income	1	2	2	6
Interest expense	(1,495)	(1,172)	(3,962)	(3,396)
Other income / (expense)	–	–	133	–
Other income / (expense), net	$ (13,252)	$ (1,170)	$ (15,585)	$ (3,390)

The restructuring of the Deerfield Loan qualifies as an extinguishment of debt in accordance with ASC Topic 470, *Debt - Modifications and Extinguishments*, and as a result, we have incurred an $11.8 million non-cash loss on debt extinguishment consisting primarily of (1) the $7.7 million difference between the reacquisition price of the Deerfield Loan and the net carrying amount of the extinguished Deerfield Loan, and (2) the $4.1 million in fair value of the Series A and Series B warrants issued to Deerfield as part of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes.

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 7, “Deerfield Loan”).

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cash interest expense	$ 150	$ 662	$ 1,451	$ 1,963
Non-cash amortization of debt discounts	138	504	1,287	1,414
Debt discount write-off	707	–	707	–
Amortization of prepaid interest expense	420	–	420	–
Amortization of debt costs	2	5	12	15
Write-off of debt costs	66	–	66	–
Total interest expense	$ 1,483	$ 1,171	$ 3,943	$ 3,392

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 Deerfield Warrants. Debt discount write-off represents the proportional write-off of unamortized debt discount at the time of a $2.5 million prepayment of principal amount outstanding under the Deerfield Loan. Amortization of prepaid interest expense represents non-cash amortization of the $5 million of Series A and Series B units Deerfield agreed to purchase in our July 2015 public offering and accept in satisfaction of $5 million of future interest payments due under the Deerfield Notes. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan, and the write-off of debt costs represents the write-off of the remaining costs at the time of the debt restructuring.

For the nine months ended September 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, as well as efforts through April 2015 to commercialize SURFAXIN, including marketing, commercial 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, collaboration agreements and other transactions, public and private equity offerings, the potential exercise of outstanding warrants and, in the future, potential secured debt facilities.

As of September 30, 2015, we had cash and cash equivalents of $46.3 million and long-term debt of $25 million under our loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 7, "Deerfield Loan"). In July 2015, we completed a registered public offering of approximately 25.1 million Series A units and 42.0 million 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 expenses). The proceeds included $5.0 million in non-cash consideration from Deerfield (discussed below). In July 2015, we amended our Deerfield Loan agreement and related notes (Deerfield Notes) to (i) prepay in cash $5.0 million of the outstanding principal amounts under the Deerfield Notes; (ii) eliminate the principal installment due in February 2017, (iii) adjust the amounts due on each of February 13, 2018 and February 13, 2019 to $12.5 million and $12.5 million, respectively, (iv) prepay $5 million future interest obligations under the Deerfield Notes, which payment was made in the form of $5 million of securities issued in connection with the July 2015 public offering, and (v) reduce the interest rate for any remaining interest due under the Deerfield Notes from 8.75% to 8.25%. Before any additional financing activities, we anticipate that we will have sufficient cash available to support our AEROSURF phase 2 clinical program, pay our current debt service and fund our operations through the first quarter of 2017.

Under our collaboration agreement with Battelle, we 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 project plan cost of up to $11.85 million to complete Stage 2 (development) and Stage 3 (design verification and testing) of the project plan, which will be shared equally. Accordingly, we expect that our 50% share of the project plan cost for Stage 2 and Stage 3 will be up to approximately $6 million and, following the completion of Stage 3 in mid-2016, we expect to 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 at no more than the anticipated shared cost to us of up to approximately $6 million. 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 $2.4 million and expect to defer aggregate payments of up to approximately $4.0 million at certain times throughout the term of the project.

We do not expect to generate any revenue from the sale of approved products for at least the next several years. To secure the significant additional infusions of capital that we will need to execute our business strategy, advance our AEROSURF development program, pay our obligations and fund our operations, we will have to rely on other sources of capital. We have historically raised additional capital through public and private equity offerings as well as strategic transactions. However, as of October 30, 2015, we have only approximately 3.1 million authorized shares of common stock available for potential equity offerings. Based on the closing market price per share of our common stock on October 30, 2015 ($0.31), we would be limited to raising a maximum of approximately $1.0 million. To raise additional capital through equity offerings, we would be required first to seek stockholder approval to increase the authorized shares of common stock provided under our Amended and Restated Certificate of Incorporation, as amended (Certificate of Incorporation), a process that could require a special meeting of stockholders, be time-consuming and expensive and could prevent or impair our efforts to efficiently raise capital when needed, if at all. In addition, the large number of outstanding warrants (discussed below), including the February 2011 warrants that expire in February 2016 and are currently exercisable at a price per share of $0.19, potentially could depress the market value of our common stock, even if we otherwise are successful, and potentially make it more difficult to raise capital through equity offerings, if at all, on acceptable terms. To secure potentially non-dilutive sources of capital, we have in the past and plan in the future to consider strategic transactions, including without limitation potential strategic alliances and collaboration arrangements that could provide development and commercial expertise to support the development and, if approved, commercial introduction, of AEROSURF and other future KL_4 surfactant product candidates. 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 have been engaged in ongoing communications with several potential strategic counterparties, including in the first quarter of 2015 with respect to SURFAXIN. Such entities have expressed interest in AEROSURF, and our KL_4 surfactant and drug delivery technologies. We believe that we will be better positioned to identify and enter into alliances and other strategic transactions focused on AEROSURF if we obtain encouraging results from our AEROSURF phase 2 clinical program. In addition, we could also consider other non-dilutive financing transactions, including debt arrangements and secured financing transactions to fund investment in capital assets. There can be no assurance, however, that we will be successful in securing the capital we will require, whether through public or private equity offerings, strategic alliances, collaboration agreements or other strategic transactions, or through debt arrangements or the financing of capital assets. Failure to secure the necessary capital could have a material adverse effect on our business, financial condition and results of operations.

As of September 30, 2015, we had outstanding warrants to purchase approximately 121.6 million shares of our common stock at various prices, exercisable on different dates into 2024. This includes:

- warrants issued in July 2015, including (i) warrants to purchase up to approximately 67.1 million shares of common stock at an initial exercise price of $0.70 per share, and (ii) pre-funded warrants to purchase up to 42.0 million shares of common stock at an exercise price of $0.60 per share, of which the entire purchase price was pre-paid upon issuance. The July 2015 warrants are exercisable in whole or in part at any time for cash or through a cashless exercise through July 22, 2022. The July 2015 pre-funded warrants are fully paid and may be exercised at any time through July 22, 2022;
- warrants issued in February 2011 to purchase up to approximately 3.8 million shares of common that contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-current exercise price of the warrants. The exercise price of these warrants was adjusted in connection with our July 2015 public offering to $0.19 per share. The February 2011 warrants expire on February 22, 2016; and
- warrants issued to Deerfield in connection with the Deerfield Loan to purchase up to 7.0 million shares of common stock at an exercise price of $2.81 per share (Deerfield Warrants). The Deerfield Warrants may be exercised for cash or through a cashless exercise at any time through February 13, 2020. In lieu of paying cash upon exercise, the holders of the Deerfield Warrants 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.

There can be no assurance that the price of our common stock will achieve a level greater than the exercise price of the July 2015 warrants or the Deerfield 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. Upon exercise of the July 2015 pre-funded warrants, which were fully-paid at issuance, we would issue the shares to the holders and receive no additional proceeds. If the holders of the February 2011 warrants choose to exercise their warrants at any time prior to the expiration date in February 2016, we potentially could receive proceeds of up to approximately $0.7 million; however, such exercises could be accompanied by increased selling activity in the Nasdaq market and the market value of our common stock could decline.

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. *See*, Note 1, “The Company and Description of Business.” Although there can be no assurance, we expect that we may have opportunities in the future to participate in similar programs.

If in the future we are unable to fund our capital requirements, we likely will not have sufficient cash flow and liquidity to fund our business operations and pay our debt service, which could have a material adverse effect on our business and operations. In that event, we may be forced to severely 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.

As of September 30, 2015, there were 250 million shares of common stock authorized under our Certificate of Incorporation and approximately 3.1 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 Certificate of Incorporation, 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, our ATM Program and upon exercise of outstanding warrants.

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). 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 do not achieve compliance with the Minimum Bid Price Requirement prior to December 28, 2015, 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 September 30, 2015, we had cash and cash equivalents of $46.3 million compared to $44.7 million as of December 31, 2014. Cash outflows for the nine months ended September 30, 2015 consisted of $25.9 million used for ongoing operating activities and $0.2 million for investing activities. Cash provided by financing activities consisted of $32.6 million of proceeds from the July 2015 registered public offering and $0.1 million of proceeds from the exercise of warrants, partially offset by $5.0 million in principal payments on the Deerfield Loan and $0.1 million in repayment of equipment loans.

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2015 and 2014 was $25.9 million and $31.1 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 nine months ended September 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 nine months ended September 30, 2014 represents capital expenditures of $0.7 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2015 and 2014 was $27.7 million and $0.4 million. Net cash provided by financing activities consisted of $32.6 million of proceeds from the July 2015 registered public offering and $0.1 million of proceeds from the exercise of warrants, partially offset by $5.0 million in principal payments on the Deerfield Loan and $0.1 million in repayment of equipment loans. Net cash provided by financing activities for the nine months ended September 30, 2014 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 September 30, 2015, after reserves for outstanding unexercised warrants and amounts remaining under our ATM Program, approximately $138.1 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 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 was made pursuant to a preliminary prospectus supplement dated July 16, 2015 to the 2014 Universal Shelf.

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 Certificate of Incorporation 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, our ATM Program 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 that will end on February 11, 2016. 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 September 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 September 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 subsequent Quarterly Reports on 10-Q. The risks and uncertainties discussed in our 2014 Form 10-K and Quarterly Reports on Form 10-Q 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 our 2014 Form 10-K and the Quarterly Reports on Form 10-Q 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.

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: November 5, 2015

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

Date: November 5, 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
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101.1	The following consolidated financial statements from the Discovery Laboratories, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in Extensive Business Reporting Language (“XBRL”): (i) Balance Sheets as of September 30, 2015 (unaudited) and December 31, 2014, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2015 and September 30, 2014 (iii) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2015 and September 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 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: November 5, 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: November 5, 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 September 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: November 5, 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.