

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 March 31, 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

(State or other jurisdiction of incorporation or organization)

94-3171943

(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 May 1, 2015, there were outstanding 85,748,500 shares of the registrant's common stock, par value \$0.001 per share.

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements provide our current expectations about future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time during which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, and manufacturing plans, and our expectations related to our development plans and regulatory strategy to secure marketing authorization for our products under development, starting with AEROSURF®; our research and development programs, planning for development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant pipeline, and our capillary aerosol generator (CAG) for delivery of aerosolized medications; our expectations, timing and anticipated outcomes of submitting regulatory filings for our products; our plans for the manufacture and procurement of our KL4 surfactant, active pharmaceutical ingredients (APIs), excipients, materials and medical devices; and plans regarding potential strategic alliances and other collaborative arrangements to develop, manufacture and market our products.

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

- the risk that following our decision in April 2015 to cease the commercialization of SURFAXIN®, our inability to generate revenues for the next several years may make it more difficult to secure the additional capital (whether from strategic alliances, equity financings or other sources) we will require 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. To the extent that we raise capital through additional equity financings, such additional financings would result in equity dilution;
- the risk that our AEROSURF phase 2 clinical program may be interrupted, delayed, or fail, which will harm our business;
- 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 may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us with the development of our KL4 surfactant products, beginning with AEROSURF, and, if approved, commercialization of AEROSURF in markets outside the U.S.; and potentially support the development and, if approved, commercialization, of our other pipeline products;
- risks 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 the transfer of our manufacturing technology to contract manufacturing organizations (CMOs) and assemblers;
- risks relating to our CMOs' ability to manufacture our KL4 surfactant in lyophilized dosage form, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests;
- risks relating to our and our CMOs' ability to develop and manufacture combination drug/device products based on our CAG technology for preclinical and clinical studies of our product candidates and, ultimately if approved, for commercialization;
- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems in manufacturing our KL4 surfactant drug product and the APIs used in the manufacture of our drug products, CAG devices and other materials on a timely basis or in an amount sufficient to support our needs;
- risks relating to our 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 investment; moreover, we may be required to seek the consent of Deerfield to enter into certain strategic transactions;
- risks that unfavorable credit and financial markets may adversely affect our ability to fund our activities, through our ATM Program or otherwise, and that our ATM Program may be exhausted or expire in February 2016 unutilized; and that additional equity financings could result in substantial equity dilution or result in a downward adjustment to the exercise price of five-year warrants that we issued in February 2011 (which contain price-based anti-dilution adjustments);
- risks related to our efforts to gain regulatory approval in the U.S. and elsewhere for our drug products, medical device and combination drug/device product candidates, including AEROSURF, and our lyophilized KL4 surfactant, which we are developing to be the drug component of AEROSURF;
- 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; and
- other risks and uncertainties as detailed in "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 16, 2015, and our other filings with the SEC and any amendments thereto, and in the documents incorporated by reference in this report.

Pharmaceutical, biotechnology and medical technology companies have suffered significant setbacks conducting clinical trials, even after obtaining promising earlier preclinical and clinical data. Moreover, data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products, and may never become profitable.

The forward-looking statements contained in this report or the documents incorporated by reference herein speak only as of their respective dates. Factors or events that could cause our actual results to differ may emerge from time to time and it is not possible for us to predict them all. Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

Trademark Notice

AEROSURF®, **AFECTAIR®**, **DISCOVERYLABS®**, **INSPIRED INNOVATION®**, **SURFAXIN®**, **SURFAXIN LS™**, and **WARMING CRADLE®** are registered and common law trademarks of Discovery Laboratories, Inc. (Warrington, PA).

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets

(in thousands, except per share data)

	March 31, 2015 (Unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 35,583	\$ 44,711
Inventory, net	–	27
Prepaid expenses and other current assets	576	821
Total current assets	36,159	45,559
Property and equipment, net	1,665	1,637
Restricted cash	225	225
Other assets	73	78
Total assets	<u>\$ 38,122</u>	<u>\$ 47,499</u>
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 702	\$ 350
Accrued expenses	7,224	6,116
Deferred revenue	–	43
Common stock warrant liability	1,289	1,258
Equipment loans, current portion	42	62
Total current liabilities	9,257	7,829
Long-term debt, \$30,000 net of discount of \$9,143 at March 31, 2015 and \$9,698 at December 31, 2014	20,857	20,302
Other liabilities	196	169
Total liabilities	30,310	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; 85,769,392 and 85,607,806 shares issued at March 31, 2015 and December 31, 2014, respectively; 85,748,500 and 85,586,914 shares outstanding at March 31, 2015 and December 31, 2014, respectively	86	86
Additional paid-in capital	546,967	546,175
Accumulated deficit	(536,187)	(524,008)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total stockholders' equity	7,812	19,199
Total liabilities & stockholders' equity	<u>\$ 38,122</u>	<u>\$ 47,499</u>

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 March 31,	
	2015	2014
Revenues:		
Product sales	\$ 7	\$ 28
Grant revenue	184	3
	<u>191</u>	<u>31</u>
Expenses:		
Cost of product sales	929	781
Research and development	7,082	5,590
Selling, general and administrative	3,353	4,423
	<u>11,364</u>	<u>10,794</u>
Operating loss	(11,173)	(10,763)
Change in fair value of common stock warrant liability	(31)	378
Other income / (expense):		
Interest and other income	233	2
Interest and other expense	(1,208)	(1,093)
	<u>(975)</u>	<u>(1,091)</u>
Other income / (expense), net	(975)	(1,091)
Net loss	<u>\$ (12,179)</u>	<u>\$ (11,476)</u>
Net loss per common share – Basic and diluted	\$ (0.14)	\$ (0.14)
Weighted-average number of common shares outstanding – basic and diluted	85,589	84,728

See notes to consolidated financial statements.

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

(in thousands)

	Three Months Ended	
	March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (12,179)	\$ (11,476)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	425	149
Provision for excess inventory	(174)	766
Stock-based compensation and 401(k) Plan employer match	792	954
Fair value adjustment of common stock warrants	31	(378)
Amortization of discount on long-term debt	555	439
Changes in:		
Inventory	201	(1,083)
Accounts receivable	–	67
Prepaid expenses and other current assets	245	75
Accounts payable	352	1,145
Accrued expenses	1,108	(1,059)
Deferred revenue	(43)	(54)
Other liabilities	27	176
Net cash used in operating activities	<u>(8,660)</u>	<u>(10,279)</u>
Cash flows from investing activities:		
Purchase of property and equipment	<u>(448)</u>	<u>(497)</u>
Net cash used in investing activities	<u>(448)</u>	<u>(497)</u>
Cash flows from financing activities:		
Proceeds from exercise of common stock options	–	31
Proceeds from exercise of common stock warrants	–	423
Repayment of equipment loans	<u>(20)</u>	<u>(19)</u>
Net cash (used in) provided by financing activities	<u>(20)</u>	<u>435</u>
Net decrease in cash and cash equivalents	(9,128)	(10,341)
Cash and cash equivalents – beginning of period	<u>44,711</u>	<u>86,283</u>
Cash and cash equivalents – end of period	<u>\$ 35,583</u>	<u>\$ 75,942</u>
Supplementary disclosure of cash flows information:		
Interest paid	\$ 649	\$ 649

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 drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. Despite significant investments in SURFAXIN, revenue growth was slower than expected. In mid-April 2015, after evaluating potential strategic alternatives, none of which could be accomplished on acceptable terms within a reasonable period, we announced that we are ceasing the commercialization of SURFAXIN to conserve our resources to advance the AEROSURF® clinical program.

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

AEROSURF is an investigational combination drug/device product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG) technology. With AEROSURF, neonatologists potentially will be able to administer aerosolized KL4 surfactant to premature infants supported with nCPAP alone, without having to resort to invasive intubation and mechanical ventilation. By enabling delivery of our aerosolized KL4 surfactant using less invasive means, we believe that AEROSURF will address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated. We recently completed enrollment in our AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age (GA) with RDS and are on track to release the results in mid-May. We currently are preparing for the next phase of this clinical program, which will include evaluating the safety and tolerability of aerosolized KL4 surfactant in premature infants 26 to 28 week GA, as well as the planned AEROSURF phase 2b clinical program.

In the future, we expect to leverage the information, data and knowledge that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a potential product pipeline to address serious critical care respiratory conditions in children and adults in pediatric and adult intensive care units. While we currently are focused primarily on the development of AEROSURF through phase 2 clinical trials in RDS, we have explored and plan in the future to explore potential opportunities to address such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI, where there are no currently approved therapies other than supportive respiratory care. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis. We believe that we have an opportunity to develop a broad pipeline of KL4 surfactant products to address these and other conditions.

Note 2 – Liquidity Risks and Management’s Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, and, more recently, commercialization and medical affairs activities, and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, debt facilities, strategic alliances, committed equity financing facilities, at-the-market equity programs, and capital equipment financings. We expect to fund our business operations in the future primarily through all or a combination of strategic alliances, public equity offerings, including under our ATM Program (*see*, Note 10, “Stockholders’ Equity – At-the-Market Program (ATM Program),” in the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2014 that we filed with the Securities and Exchange Commission (SEC) on March 16, 2015 (2014 Form 10-K)), the potential exercise of outstanding warrants, and secured debt facilities.

We recently announced our decision to cease commercialization activities for our only approved product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS (*see*, Note 1, “The Company and Description of Business”). As a result, for the next several years, if ever, we do not expect to generate any revenue from the sale of approved products. Thus, to secure the significant additional infusions of capital that we will need to execute our business strategy, advance our development programs, pay debt obligations and fund our operations, we will have to rely on non-sales sources of capital, including potentially: (i) strategic alliances and collaboration arrangements, which could provide development and commercial expertise as well as financial resources to support the development and, if approved, commercial introduction of, our KL4 surfactant pipeline product candidates, beginning with AEROSURF, in markets outside the U.S., (ii) public and private equity offerings, including potentially pursuant to our ATM Program, (iii) secured debt arrangements to provide working capital and fund investment in capital assets, and (iv) the potential exercise of outstanding warrants (discussed below). In addition, we have in the past collaborated with research organizations and universities to assess potential application of our KL4 surfactant in studies funded in part through various U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical program and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological, and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. We expect that we may have opportunities in the future to participate in similar programs.

As of March 31, 2015, we had cash and cash equivalents of \$35.6 million and long-term debt of \$30 million under our loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 9, “Deerfield Loan,” in the Notes to Consolidated Financial Statements in our 2014 Form 10-K). Under our ATM Program, subject to market conditions, we may sell up to approximately \$23 million of common stock at such times and in such amounts that we deem appropriate, subject to a 3% commission. We also will consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions. Under our collaboration agreement with Battelle Memorial Institute (Battelle), we have agreed to share equally in the planned cost of a project to develop our CAG device for use in our planned AEROSURF phase 3 clinical program and, if approved, initial commercialization. If we are able to successfully complete our collaboration with Battelle as currently planned, we anticipate that our investment through the end of 2016 will be approximately \$6 million to \$8 million for all device development activities to be in a position to manufacture CAG devices, ADPs and related components for use in the planned AEROSURF phase 3 clinical program and, if approved, initial commercialization. In addition, at our discretion from time to time, we may defer payment of amounts due to Battelle under our collaboration agreement in respect of our share of development costs for up to 12 months. Any such deferred amounts that are outstanding for more than 90 days will bear interest at a rate of 12% per annum. In addition, we have agreed that the aggregate amounts deferred beyond 30 days will not exceed our available cash and cash equivalents. We currently have deferred certain payments and expect to defer payments of up to approximately \$3.0 million through the first quarter of 2016. Before any additional financings and taking into account our recent decision to cease our SURFAXIN commercial activities and allow our real property lease at our manufacturing facility in Totowa, NJ (Totowa Facility) to expire on June 30, 2015 in accordance with its terms, we anticipate that we will have sufficient cash available to support our AEROSURF clinical program, pay our debt service obligations and fund our operations through the first quarter of 2016.

To secure the capital required to fund our development programs, an important priority for us is to identify strategic transactions that could provide additional capital and strategic resources to support the continued development and, if approved, commercial introduction of AEROSURF for RDS and our other potential KL4 surfactant products in markets outside the U.S. For AEROSURF, we seek a significant strategic alliance with a partner that has broad experience in markets outside the U.S., including regulatory and product-development expertise and, if AEROSURF is approved, an ability to support the commercial introduction of AEROSURF in selected markets outside the U.S. Such alliances typically also would provide financial resources, in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. We believe that we will be better positioned to identify and enter into a significant strategic alliance for AEROSURF if we obtain encouraging results from the AEROSURF phase 2 clinical program.

As of March 31, 2015, we had outstanding warrants to purchase approximately 14.6 million shares of our common stock at various prices, exercisable on different dates into 2024. This includes warrants to purchase 7 million shares that were issued to Deerfield in connection with the Deerfield Loan at an exercise price of \$2.81 per share (Deerfield Warrants). The Deerfield Warrants may be exercised for cash or on a cashless basis. In lieu of paying cash upon exercise, the holders also may elect to reduce the principal amount of the Deerfield Loan in an amount sufficient to satisfy the exercise price of the Deerfield Warrants. In addition to the Deerfield Warrants, we have outstanding warrants issued in February 2011 to purchase approximately 4.6 million shares of common stock that expire in February 2016 and contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. These warrants currently have an exercise price of \$1.50 per share. If the market price of our common stock should exceed \$1.50 at any time prior to the expiration date of these warrants (February 2016) and if the holders determine in their discretion to exercise these warrants (and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants), we potentially could receive up to approximately \$6.8 million. There can be no assurance that the price of our common stock will achieve the needed level, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

Our ability to execute our business plan will depend upon our ability to secure the necessary capital. If we are unable to secure sufficient additional capital, through strategic and collaborative arrangements with potential partners and/or future debt and equity financings, we will not have sufficient cash flows and liquidity to fund our business operations and pay our debt service. In that event, we may be forced to further limit our development programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. If the market price of our common stock should decline below \$1.00 and remain at that level for 30 consecutive business days, we would be out of compliance with Nasdaq requirements for listing on the Nasdaq Capital Market and would be subject to potential delisting. If we were then unable to re-achieve compliance with the Nasdaq listing requirements within 180 days after receipt of a delisting notice, we would be subject to delisting, which likely would further impair the liquidity and value of our common stock. 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.

Our future capital requirements will depend upon many factors, including our efforts to (i) advance the AEROSURF development program to completion of the phase 2 clinical trials in RDS as planned; (ii) assure long-term continuity of supply for our lyophilized KL4 surfactant drug product with our contract manufacturing organization (CMO), (iii) through our collaboration arrangement with Battelle, advance the development of our CAG for use in a planned phase 3 clinical program and, if approved, early commercial activities, (iv) prepare for and conduct an AEROSURF phase 3 clinical program, and (v) secure one or more strategic alliances or other collaboration arrangements to support our development programs and commercialization of our approved products, if any, in markets outside the U.S. We believe that we will be better positioned to enter into a significant strategic alliance for AEROSURF if we obtain encouraging results from the AEROSURF phase 2 clinical program.

There can be no assurance (i) that our AEROSURF development program will be successful within our anticipated time frame, if at all, (ii) that we will be able to secure long-term continuity of drug product supply of our lyophilized KL4 surfactant, (iii) that we will be able to secure regulatory marketing authorization for AEROSURF and our other potential KL4 surfactant product candidates in the U.S. and other markets, (iv) that any of our approved products will be commercially viable, (v) that the ATM Program will be available when needed, if at all, or (vi) that we otherwise will be able to obtain additional capital when needed and on acceptable terms. We will require significant additional capital to execute our business strategy, pay debt service and sustain operations. Failure to secure the necessary additional capital when needed would have a material adverse effect on our business, financial condition and results of operations. Even if we succeed in our efforts and subsequently commercialize our products, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of March 31, 2015, there were 250 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 135.9 million shares of common stock were available for issuance and not otherwise reserved.

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information in accordance with the instructions to 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 months ended March 31, 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. The cost of such benefits is accrued over the remaining service period.

In September 2013, we implemented an employee severance and retention plan for employees at our Totowa Facility to minimize employee turnover and encourage employees to remain with us through any potential plant closing. The plan provides for severance for non-union employees and retention bonuses for management. The total cash amount expected to be paid for severance and retention under this plan assuming a June 2015 plant closing is approximately \$1.0 million. The plan-related expense for the three months ended March 31, 2015 was \$0.1 million and is included in research and development expense and cost of product sales. The related accrued liability is \$0.7 million as of March 31, 2015. In addition, at the Totowa Facility, there are 12 employees who are subject to a collective bargaining agreement under which they will be eligible to receive severance payments when the Totowa Facility is closed. The related accrued liability is \$0.4 million as of March 31, 2015.

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 have ceased manufacturing activities at our Totowa Facility, which will be closed prior to the expiration of our lease on June 30, 2015, and the remaining \$0.3 million in employee severance cost will be incurred in the second quarter of 2015. *See*, Note 8, “Subsequent Events.”

Long-lived assets

Our long-lived assets, primarily consisting of 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. As of March 31, 2015, we had manufacturing equipment and leasehold improvements dedicated to the manufacture of SURFAXIN with a carrying value of \$0.4 million. At March 31, 2015, we evaluated these assets for impairment and concluded that the undiscounted cash flows exceed the carrying value and that the assets are, therefore, not impaired. In April 2015, these assets will be considered assets held for sale and valued at the lower of carrying amount or fair value less cost to sell. A loss will be recognized, if any, for any initial adjustment of the long-lived asset’s carrying amount to its fair value less cost to sell.

Product Sales

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

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 March 31, 2015 and 2014, the number of shares of common stock potentially issuable upon the exercise of stock options and warrants was 23.3 million and 21.3 million shares, respectively.

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.

For the three months ended March 31, 2015 and 2014, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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

Recent accounting pronouncements

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

Note 4 – Fair Value of Financial Instruments

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

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

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

Fair Value on a Recurring Basis

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

	Fair Value	Fair value measurement using		
	March 31, 2015	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	\$ 35,583	\$ 35,583	\$ –	\$ –
Certificate of Deposit	225	225	–	–
Total Assets	\$ 35,808	\$ 35,808	\$ –	\$ –

Liabilities:				
Common stock warrant liability	\$ 1,289	\$ –	\$ –	\$ 1,289

	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 table below summarizes the activity of Level 3 inputs measured on a recurring basis for the three months ended March 31, 2015 and 2014:

<i>(in thousands)</i>	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2014	\$ 1,258
Change in fair value of common stock warrant liability	31
Balance at March 31, 2015	\$ 1,289

<i>(in thousands)</i>	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2013	\$ 5,425
Exercise of warrants	(375)
Change in fair value of common stock warrant liability	(378)
Balance at March 31, 2014	\$ 4,672

The significant unobservable inputs used in the fair value measurement of the common stock warrants measured on a recurring basis are the historical volatility of our common stock market price, expected term of the applicable warrants, and the risk-free interest rate based on the U.S. Treasury yield curve in effect at the measurement date. In addition to the significant unobservable inputs noted above, certain fair value measurements also take into account an assumption of the likelihood and timing of the occurrence of an event that would result in an adjustment to the exercise price in accordance with the anti-dilutive pricing provisions in 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	March 31, 2015	December 31, 2014
Historical volatility	61%	55% – 84%
Expected term (in years)	0.9	0.1 – 1.1
Risk-free interest rate	0.25%	0.03% – 0.31%

Fair Value of Long-Term Debt

At March 31, 2015, the estimated fair value of the Deerfield Loan (see, Note 6, “Deerfield Loan”) was \$21.3 million compared to a carrying value, net of discounts, of \$20.9 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. 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.

Note 5 – Common Stock Warrant Liability

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

We issued warrants on February 22, 2011 in connection with a February 2011 public offering that expire on February 22, 2016 and had a fair value at issuance of \$8.0 million. As of March 31, 2015, there were 4.6 million warrant shares potentially issuable under these warrants with a fair value of \$1.3 million. These warrants contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. Although by their express terms, these warrants are not subject to potential cash settlement, due to the nature of the anti-dilution provisions, they are classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model. The exercise price of these warrants at issuance of \$3.20 was adjusted downward to \$2.80 per share at the time of a March 2012 public offering, and further adjusted to \$1.50 per share at the time of a May 2013 public offering.

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

No warrants were exercised during the three months ended March 31, 2015 and 2014.

Note 6 – Deerfield Loan

Long-term debt consists solely of amounts due under the \$30 million loan Deerfield Loan with Deerfield for the periods presented:

<i>(in thousands)</i>	March 31, 2015	December 31, 2014
Note payable	\$ 30,000	\$ 30,000
Unamortized discount	(9,143)	(9,698)
Long-term debt, net of discount	<u>\$ 20,857</u>	<u>\$ 20,302</u>

The principal amount of the loan is payable in three \$10 million annual installments beginning in February 2017, provided that the amounts payable in February 2017 and 2018 may be deferred if certain financial milestones are achieved. See, Note 9, “Deerfield Loan,” in the Notes to Consolidated Financial Statements in our 2014 Form 10-K. Accordingly, if the milestones are achieved in each year, payment of the principal amount could be deferred until the sixth anniversary date of the loan, on February 13, 2019.

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

<i>(in thousands)</i>	Three months ended	
	March 31,	
	2015	2014
Cash interest expense	\$ 647	\$ 647
Non-cash amortization of debt discount	554	439
Amortization of debt costs	5	5
Total interest expense	\$ 1,206	\$ 1,091

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

In connection with the Deerfield Loan, we issued the Deerfield Warrants to purchase 7.0 million shares of our common stock at an exercise price of \$2.81 per share that expire on February 13, 2019. The Deerfield Warrants are derivatives that qualify for an exemption from liability accounting provided in ASC 815 and are classified as equity. See, Note 9, “Deerfield Loan,” in the Notes to Consolidated Financial Statements in our 2014 Form 10-K.

Note 7 – Stock Options and Stock-Based Employee Compensation

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

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

	March 31,	
	2015	2014
Weighted average expected volatility	83%	100%
Weighted average expected term	5.6 years	5.4 years
Weighted average risk-free interest rate	1.5%	1.6%
Expected dividends	–	–

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

<i>(in thousands)</i>	Three Months Ended	
	March 31,	
	2015	2014
Research & Development	\$ 213	\$ 248
Selling, General & Administrative	386	455
Total	\$ 599	\$ 703

Note 8 – Subsequent Event

We evaluated all events or transactions that occurred after March 31, 2015 through the date we issued these financial statements. During this period, we noted one subsequent event as described below:

Effective April 16, 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 for respiratory diseases, beginning with AEROSURF.

In connection with the restructuring, we reduced our workforce by 50 employees, from 108 to 58 employees. The reduction in workforce affected a number of key functions, but focused primarily on commercial infrastructure and SURFAXIN manufacturing at our Totowa Facility. Affected employees are entitled to receive certain severance and other benefits consistent with their position and tenure with us. In connection with the reduction, we expect to record a one-time restructuring charge of approximately \$2.5 million to \$3.0 million in the second quarter of 2015.

In connection with the restructuring, effective April 17, 2015 we terminated the Employment Agreement dated April 1, 2013 (Employment Agreement) of our Senior Vice President and Chief Operating Officer (the Executive). In connection therewith, upon execution by the Executive of a plenary release in form satisfactory to us, he became entitled under his Employment Agreement to receive certain severance and other benefits. In addition to any benefits that were otherwise due under our vested plans or other policies, the Executive will receive the following payments and benefits: (i) a pro rata bonus equal to that percent of the Executive's Annual Bonus Amount (as defined in the Employment Agreement) that corresponds to that percent of days that the Executive was employed by us in 2015, reduced to reflect the same percent of his pro rata Annual Bonus Amount that corresponds to the percent of the aggregate Annual Bonus Amounts actually paid to other contract executives with respect to 2015, payable at the time that our other contract executives are paid bonuses; (ii) a severance amount equal to the sum of the Executive's base salary then in effect and his Annual Bonus Amount, payable in equal installments from April 17, 2015 to April 17, 2016 (the Severance Period); and (iii) all vested stock options, restricted stock grants and other similar equity awards held by the Executive shall continue to be exercisable during the Severance Period. From and after the effective date of termination, all of the Executive's unvested stock options were forfeited in accordance with the terms of our 2011 Long-Term Incentive Plan. In addition, the Executive also is subject to non-competition and non-solicitation restrictions for 12 months and 18 months, respectively, after the date of termination under a separate confidentiality agreement. All of our obligations under the Employment Agreement will cease if at any time during the Severance Period the Executive engages in a material breach of the Employment Agreement and fails to cure such breach within five business days after receipt from us of notice of such breach.

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).

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 drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. Despite significant investments in SURFAXIN, revenue growth was slower than expected. In mid-April 2015, after evaluating potential strategic alternatives for SURFAXIN, none of which could be accomplished on acceptable terms within a reasonable period, we announced that we are ceasing the commercialization of SURFAXIN to conserve our resources to advance the AEROSURF® clinical program.

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

AEROSURF is an investigational combination drug/device product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG) technology. With AEROSURF, neonatologists potentially will be able to administer aerosolized KL4 surfactant to premature infants supported with nCPAP alone, without having to resort to invasive intubation and mechanical ventilation. By enabling delivery of our aerosolized KL4 surfactant using less invasive means, we believe that AEROSURF will address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated. We recently completed enrollment in an AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age (GA) with RDS and are on track to release the results in mid-May. We currently are preparing for the next phase of this clinical program, which will include evaluating the safety and tolerability of aerosolized KL4 surfactant in premature infants 26 to 28 week GA, as well as the planned AEROSURF phase 2b clinical program.

In the future, we expect to leverage the information, data and know-how that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a potential product pipeline to address serious critical care respiratory conditions in children and adults in pediatric and adult intensive care units. While we currently are focused primarily on the development of AEROSURF through phase 2 clinical trials, we have explored and plan in the future to explore potential opportunities to address such respiratory conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI, where there are no currently approved therapies other than supportive respiratory care. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis. We believe that we have an opportunity to develop a broad pipeline of KL4 surfactant products to address these and other conditions.

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:

- SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the first such alternative to animal-derived surfactants. We initiated the commercial introduction of SURFAXIN in late 2013 and made significant cash investments to support manufacturing, quality systems, supply chain and distribution, marketing, medical and commercial activities for SURFAXIN. In 2014, cash outflows in support of operating activities for SURFAXIN were approximately \$19.0 million. Notwithstanding, revenue growth was slower than expected. After evaluating potential strategic alternatives for SURFAXIN, none of which could be accomplished on acceptable terms within a reasonable period, in April 2015, we announced that we are ceasing the commercialization of SURFAXIN.
- As a consequence of our decision to cease the commercialization of SURFAXIN, we are no longer planning to advance the development of SURFAXIN LS™, our lyophilized KL4 surfactant and life-cycle extension of SURFAXIN.
- Our recently completed AEROSURF phase 2a clinical trial was an open label, single-dose study with the primary goal of evaluating the safety and tolerability of aerosolized KL4 surfactant drug product administered in escalating inhaled doses in 48 premature infants 29 to 34 week GA who are receiving nCPAP for RDS, compared to infants receiving nCPAP alone. In addition to evaluating safety and tolerability, another key objective of this trial is to establish proof of concept for our proprietary technology platform with (1) physiological data indicating that aerosolized KL4 surfactant is being effectively delivered into the lung of premature infants, and (2) acceptable performance of the novel CAG technology in the NICU. We currently are preparing for the next phase of this clinical program, which will include evaluating the safety and tolerability of aerosolized KL4 surfactant in premature infants 26 to 28 week GA.
- We are also implementing preparatory activities for the planned AEROSURF phase 2b clinical trial, including initiation of a number of additional clinical sites and making investments to expand our clinical capabilities. The final design of the phase 2b clinical trial will be informed in part by the results of the phase 2a clinical program, and is expected to be a multicenter trial conducted at selected medical centers both within and outside the U.S. The primary objective of this trial will be to determine the optimal doses and define the expected efficacy margin. We expect that this trial will be completed in the second quarter of 2016.
- We are working with Battelle Memorial Institute (Battelle) to provide for the manufacture of a sufficient number of CAG devices and disposable AEROSURF dose packs (ADPs) to support the remainder of our phase 2 clinical program. Beginning in 2012, Battelle assisted us in the development and manufacture of a CAG device for use in our phase 2 clinical program under a Research and Development Services Agreement dated June 22, 2012 (RDSA). To facilitate the manufacture of the additional devices needed to complete the phase 2 clinical program, we recently extended the RDSA through June 30, 2016. We are also advancing our development activities under our October 2014 collaboration agreement to further develop our CAG device for use in our planned phase 3 clinical program and, if AEROSURF is approved, initial commercial activities. *See*, “Item 1 – Business – Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement,” in our 2014 Form 10-K.
- We continue to 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, we are advised that Patheon intends to close the building in which our development activities have occurred. Accordingly, we are engaged in a technology transfer of our manufacturing process to a new facility within Patheon where the phase 3 manufacturing development work will occur.

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 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 March 31, 2015 and 2014 was \$12.2 million (or \$0.14 basic net loss per share) and \$11.5 million (or \$0.14 basic net loss per share), respectively. The operating loss for the three months ended March 31, 2015 and 2014 was \$11.2 million and \$10.8 million, respectively.

Grant Revenue

We recognized grant revenue of \$184,000 for the three months ended March 31, 2015 under two grants discussed below.

During the second quarter of 2014, we were awarded the final \$1.9 million of a \$2.4 million Fast Track Small Business Innovation Research (SBIR) Grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). This award provides support for the ongoing phase 2a clinical trial for AEROSURF. We received and expended \$1.8 million in 2014 under this award. We previously received and expended \$0.6 million in 2011 under this grant to support development activities related to our capillary aerosol generator technology.

During the third quarter of 2014, we were awarded a Phase II SBIR grant of \$1.0 million from the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH to support the development of our aerosolized KL4 surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury. We received \$0.7 million in 2014 under this award. Over the next two years, we may be awarded up to an additional \$2.0 million as part of this grant. Phase I of this grant was awarded in 2012 for \$0.6 million and we previously received and expended \$0.4 million in 2013 and \$0.2 million in 2012.

Cost of product sales

Cost of product sales for the three months ended March 31, 2015 and 2014 was \$0.9 million and \$0.8 million, respectively, and represents reserves for SURFAXIN finished goods inventories that are not anticipated to be recoverable through future commercial sale of the product. Cost of product sales for the three months ended March 31, 2015 also includes \$0.2 million in additional depreciation expense related to WARMING CRADLE® dry block heaters that are not anticipated to provide future economic benefit and have no salvage value.

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 KL4 surfactant and drug delivery technologies, they are expected to benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist 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 months ended March 31, 2015 and 2014 are as follows:

<i>(in thousands)</i>	Three Months Ended	
	March 31,	
Research and Development Expenses	2015	2014
Product development and manufacturing	\$ 4,086	\$ 3,623
Medical and regulatory operations	1,774	1,633
Direct preclinical and clinical programs	1,222	333
Total Research and Development Expenses	<u>\$ 7,082</u>	<u>\$ 5,590</u>

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of \$0.4 million for each of the three months ended March 31, 2015 and 2014.

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 March 31, 2015 increased \$0.5 million compared to the same period in 2014, due to an investment of \$0.5 million in 2015 for development activities under our collaboration agreement with Battelle for the further development of our CAG for potential use in our planned phase 3 clinical program for AEROSURF.

Medical and Regulatory Operations

Medical and regulatory operations includes (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our research and development programs; and (ii) medical affairs activities to provide scientific and medical education support related primarily to SURFAXIN, as well as our other KL4 surfactant and aerosol delivery products under development. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Medical and regulatory operations expenses for the three months ended March 31, 2015 increased \$0.1 million compared to the same period in 2014.

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 March 31, 2015 increased \$0.9 million compared to the same period in 2014 due to an increase in AEROSURF clinical trial activities, including ongoing enrollment of the phase 2a study and manufacturing of clinic-ready CAG devices to support further clinical activities and the planned AEROSURF phase 2b clinical trial.

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 have been focused initially on the management of RDS in premature infants. They currently include (i) lyophilized KL4 surfactant, which we are developing initially for use in our AEROSURF development program; (ii) our aerosol delivery technologies, including our CAG device, which currently is being used in our AEROSURF phase 2 clinical program. Under our collaboration agreement with Battelle, we and Battelle have agreed to share equally in the planned cost of a project to further develop our CAG device for use in our planned AEROSURF phase 3 clinical program and, if approved, initial commercialization; and (iii) AEROSURF phase 2 clinical trial activities and preparatory work for the planned AEROSURF phase 3 clinical program.

To prepare for initiation of the next AEROSURF phase 2a clinical trial, our planned AEROSURF phase 2b clinical trial and the phase 3 clinical program, we plan to make additional investments in our development capabilities, including for manufacturing development of our lyophilized KL4 surfactant, manufacture of additional CAG devices to complete our phase 2 clinical program, and further development of our CAG device under our collaboration with Battelle for our planned phase 3 clinical program, and 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 trial and execute the later stages of the planned AEROSURF clinical development program.

Currently, we are focusing our development efforts primarily on RDS and the development of AEROSURF through the phase 2 clinical program to the planned phase 3 clinical program. In the future, we expect to leverage the information, data and knowledge that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a potential product pipeline to address serious critical care respiratory conditions in children and adults in pediatric and adult intensive care units. We have explored and plan in the future to further explore potential opportunities to address such respiratory conditions as ALL, including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALL, and influenza-induced ALL, where there are no currently approved therapies other than supportive respiratory care. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, diseases involving mucociliary clearance disorders, such as COPD and cystic fibrosis.

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

<i>(in thousands)</i>	Three Months Ended March 31,	
	2015	2014
Selling, General and Administrative Expenses	<u>\$ 3,353</u>	<u>\$ 4,423</u>

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 months ended March 31, 2015 decreased \$1.1 million compared to the same period in 2014 due to our efforts during the first quarter of 2015 to limit commercial and marketing expenses while evaluating strategic alternatives for SURFAXIN.

Change in Fair Value of Common Stock Warrant Liability

<i>(in thousands)</i>	Three Months Ended March 31,	
	2015	2014
Change in fair value of common stock warrant liability	<u>\$ (31)</u>	<u>\$ 378</u>

We account for common stock warrants in accordance with applicable accounting guidance provided in Accounting Standards Codification (ASC) Topic 815 “*Derivatives and Hedging – Contracts in Entity’s Own Equity*” (ASC 815), either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Derivative warrant liabilities are valued at the date of initial issuance and as of each subsequent balance sheet date using the Black-Scholes or trinomial pricing models, depending on the terms of the applicable warrant agreement. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as “Change in the fair value of common stock warrant liability.” *See*, Note 5, “Common Stock Warrant Liability,” in the Notes to Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q, and “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Change in Fair Value of Common Stock Warrant Liability” 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)

<i>(in thousands)</i>	Three months ended	
	March 31,	
	2015	2014
Interest income	\$ 1	\$ 2
Interest expense	(1,208)	(1,093)
Other income / (expense)	232	–
Other income / (expense), net	<u>\$ (975)</u>	<u>\$ (1,091)</u>

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

Interest expense consists of interest expense associated with the Deerfield Loan (*see*, Note 6, “Deerfield Loan,” in the Notes to Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q).

Other income / (expense) primarily consists of proceeds from the sale of Commonwealth of Pennsylvania research and development tax credits.

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

<i>(in thousands)</i>	Three months ended	
	March 31,	
	2015	2014
Cash interest expense	\$ 647	\$ 647
Non-cash amortization of debt discount	554	439
Amortization of debt costs	5	5
Total interest expense	<u>\$ 1,206</u>	<u>\$ 1,091</u>

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

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, and, more recently, commercialization and medical affairs activities, and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, debt facilities, strategic alliances, committed equity financing facilities, at-the-market equity programs, and capital equipment financings. We expect to fund our business operations in the future primarily through all or a combination of strategic alliances, public equity offerings, including our ATM Program (*see*, “– At-the-Market Program (ATM Program)”), the potential exercise of outstanding warrants, and secured debt facilities.

We recently announced our decision to cease commercialization activities for our only approved product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS (*see*, “Overview – Business and Pipeline Programs Update”). As a result, for the next several years, if ever, we do not expect to generate any revenue from the sale of approved products. Thus, to secure the significant additional infusions of capital that we will need to execute our business strategy, advance our development programs, pay debt obligations and fund our operations, we will have to rely on non-sales sources of capital, including potentially: (i) strategic alliances and collaboration arrangements, which could provide development and commercial expertise as well as financial resources to support the development and, if approved, commercial introduction of, our KL4 surfactant pipeline product candidates, beginning with AEROSURF, in markets outside the U.S., (ii) public and private equity offerings, including potentially pursuant to our ATM Program, (iii) secured debt arrangements to provide working capital and fund investment in capital assets, and (iv) the potential exercise of outstanding warrants (discussed below). In addition, we have in the past collaborated with research organizations and universities to assess potential application of our KL4 surfactant in studies funded in part through various U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical program and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological, and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. We expect that we may have opportunities in the future to participate in similar programs.

As of March 31, 2015, we had cash and cash equivalents of \$35.6 million and long-term debt of \$30 million under our loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 9, “Deerfield Loan,” in the Notes to Consolidated Financial Statements in our 2014 Form 10-K). Under our ATM Program, subject to market conditions, we may sell up to approximately \$23 million of common stock at such times and in such amounts that we deem appropriate, subject to a 3% commission. We also will consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions. Under our collaboration agreement with Battelle, we have agreed to share equally in the planned cost of a project to develop our CAG device for use in our planned AEROSURF phase 3 clinical program and, if approved, initial commercialization. If we are able to successfully complete our collaboration with Battelle as currently planned, we anticipate that our investment through the end of 2016 will be approximately \$6 million to \$8 million for all device development activities to be in a position to manufacture CAG devices, ADPs and related components for use in the planned AEROSURF phase 3 clinical program and, if approved, initial commercialization. In addition, at our discretion from time to time, we may defer payment of amounts due to Battelle under our collaboration agreement in respect of our share of development costs for up to 12 months. Any such deferred amounts that are outstanding for more than 90 days will bear interest at a rate of 12% per annum. In addition, we have agreed that the aggregate amounts deferred beyond 30 days will not exceed our available cash and cash equivalents. We currently have deferred certain payments and expect to defer payments of up to approximately \$3.0 million through the first quarter of 2016. Before any additional financings and taking into account our recent decision to cease our SURFAXIN commercial activities and allow our real property lease at our manufacturing facility in Totowa, NJ (Totowa Facility) to expire on June 30, 2015 in accordance with its terms, we anticipate that we will have sufficient cash available to support our AEROSURF clinical program, pay our debt service obligations and fund our operations through the first quarter of 2016.

To secure the capital required to fund our development programs, an important priority for us is to identify strategic transactions that could provide additional capital and strategic resources to support the continued development and, if approved, commercial introduction of AEROSURF for RDS and our other potential KL4 surfactant products in markets outside the U.S. For AEROSURF, we seek a significant strategic alliance with a partner that has broad experience in markets outside the U.S., including regulatory and product-development expertise and, if AEROSURF is approved, an ability to support the commercial introduction of AEROSURF in selected markets outside the U.S. Such alliances typically also would provide financial resources, in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. We believe that we will be better positioned to identify and enter into a significant strategic alliance for AEROSURF if we obtain encouraging results from the AEROSURF phase 2 clinical program.

As of March 31, 2015, we had outstanding warrants to purchase approximately 14.6 million shares of our common stock at various prices, exercisable on different dates into 2024. This includes warrants to purchase 7 million shares that were issued to Deerfield in connection with the Deerfield Loan at an exercise price of \$2.81 per share (Deerfield Warrants). The Deerfield Warrants may be exercised for cash or on a cashless basis. In lieu of paying cash upon exercise, the holders also may elect to reduce the principal amount of the Deerfield Loan in an amount sufficient to satisfy the exercise price of the Deerfield Warrants. In addition to the Deerfield Warrants, we have outstanding warrants issued in February 2011 to purchase approximately 4.6 million shares of common stock that expire in February 2016 and contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. These warrants currently have an exercise price of \$1.50 per share. If the market price of our common stock should exceed \$1.50 at any time prior to the expiration date of these warrants (February 2016) and if the holders determine in their discretion to exercise these warrants (and we have an effective registration statement covering the warrant shares to be issued upon exercise of the warrants), we potentially could receive up to approximately \$6.8 million. There can be no assurance that the price of our common stock will achieve the needed level, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

Our ability to execute our business plan will depend upon our ability to secure the necessary capital. If we are unable to secure sufficient additional capital, through strategic and collaborative arrangements with potential partners and/or future debt and equity financings, we will not have sufficient cash flows and liquidity to fund our business operations and pay our debt service. In that event, we may be forced to further limit our development programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. If the market price of our common stock should decline below \$1.00 and remain at that level for 30 consecutive business days, we would be out of compliance with Nasdaq requirements for listing on the Nasdaq Capital Market and would be subject to potential delisting. If we were then unable to re-achieve compliance with the Nasdaq listing requirements within 180 days after receipt of a delisting notice, we would be subject to delisting, which likely would further impair the liquidity and value of our common stock. 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.

Our future capital requirements will depend upon many factors, including our efforts to (i) advance the AEROSURF development program to completion of the phase 2 clinical trials as planned; (ii) assure long-term continuity of supply for our lyophilized KL4 surfactant drug product with our contract manufacturing organization (CMO), (iii) through our collaboration arrangement with Battelle, advance the development of our CAG for use in a planned phase 3 clinical program and, if approved, early commercial activities, (iv) prepare for and conduct an AEROSURF phase 3 clinical program, and (v) secure one or more strategic alliances or other collaboration arrangements to support our development programs and commercialization of our approved products, if any, in markets outside the U.S. We believe that we will be better positioned to enter into a significant strategic alliance for AEROSURF if we obtain encouraging results from the AEROSURF phase 2 clinical program.

There can be no assurance (i) that our AEROSURF development program will be successful within our anticipated time frame, if at all, (ii) that we will be able to secure long-term continuity of drug product supply of our lyophilized KL4 surfactant, (iii) that we will be able to secure regulatory marketing authorization for AEROSURF and our other potential KL4 surfactant product candidates in the U.S. and other markets, (iv) that any of our approved products will be commercially viable, (v) that the ATM Program will be available when needed, if at all, or (vi) that we otherwise will be able to obtain additional capital when needed and on acceptable terms. We will require significant additional capital to execute our business strategy, pay debt service and sustain operations. Failure to secure the necessary additional capital when needed would have a material adverse effect on our business, financial condition and results of operations. Even if we succeed in our efforts and subsequently commercialize our products, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of March 31, 2015, there were 250 million shares of common stock authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 135.9 million shares of common stock were available for issuance and not otherwise reserved.

Cash Flows

As of March 31, 2015, we had cash and cash equivalents of \$35.6 million compared to \$44.7 million as of December 31, 2014. Cash outflows for the three months ended March 31, 2015 consisted of \$8.7 million used for ongoing operating activities and \$0.4 million for purchases of property and equipment. No cash was provided by financing activities for the three months ended March 31, 2015.

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2015 and 2014 was \$8.7 million and \$10.3 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2015 and 2014 represents capital expenditures of \$0.4 million and \$0.5 million, respectively.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2015 was \$20,000 and represents repayment of principal amounts due under an equipment loan. Net cash provided by financing activities for the three months ended March 31, 2014 was \$0.4 million and represents proceeds from the exercise of warrants and stock options.

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

Common Stock Offerings

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of common stock offerings. In May 2014, we filed with the SEC a universal shelf registration statement on Form S-3 (No. 333-196420) (2014 Universal Shelf) that was declared effective on June 13, 2014 for the proposed offering from time to time of up to \$250 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at the time of an offering. The 2014 Universal Shelf replaces an expired 2011 Universal Shelf. As of March 31, 2015, after reserves for outstanding unexercised warrants and amounts remaining under our ATM Program, approximately \$210.7 million remained available under the 2014 Universal Shelf. The 2014 Universal Shelf will expire in June 2017.

At-the-Market Program (ATM Program)

We have an ATM Program with Stifel, Nicolaus & Company, Incorporated (Stifel), under which Stifel, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell up to a maximum of \$25 million of our common stock over a three-year period ending February 11, 2016. We are not required to sell any shares at any time during the term of the ATM Program. We have agreed to pay Stifel a commission of 3% of gross proceeds of any sales of shares. See, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – At-the-Market Program (ATM Program) – Stifel ATM Program," in our 2014 Form 10-K. As of March 31, 2015, approximately \$23 million shares of common stock remained available under the ATM Program.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Our management, including our President and Chief Executive Officer (principal executive officer) and our 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 March 31, 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. The risks and uncertainties discussed in this Quarterly Report on Form 10-Q and described in our 2014 Form 10-K are not the only ones that may materialize. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations. If any of the risks and uncertainties discussed in this Quarterly Report on Form 10-Q or in our 2014 Form 10-K actually materialize, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment.

ITEM 6. EXHIBITS

Exhibits are listed on the Index to Exhibits at the end of this Quarterly Report. The exhibits required by Item 601 of Regulation S-K, listed on such Index in response to this Item, are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Discovery Laboratories, Inc.
(Registrant)

Date: May 11, 2015

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

Date: May 11, 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.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
10.4*	Employment Agreement dated as of December 19, 2014, by and between Discovery and Steven G. Simonson, M.D.	Filed herewith
10.5*	Amendment dated December 29, 2014 to Employment Agreement dated as of December 19, 2014, effective as of April 1, 2015, by and between Discovery and Steven G. Simonson, M.D.	Filed herewith
10.6	Amendment effective May 7, 2015, to Research and Development Services Agreement dated as of June 22, 2012, by and between Discovery and Battelle Memorial Institute.	Filed herewith
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101.1	The following consolidated financial statements from the Discovery Laboratories, Inc. Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, formatted in Extensive Business Reporting Language (“XBRL”): (i) Balance Sheets as of March 31, 2015 (unaudited) and December 31, 2014, (ii) Statements of Operations (unaudited) for the three months ended March 31, 2015 and March 31, 2014 (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2015 and March 31, 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.

* A management contract or compensatory plan or arrangement required to be filed as an exhibit to this report pursuant to Item 15(b) of Form 10-Q.

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of December 19, 2014, by and between Discovery Laboratories, Inc., a Delaware corporation (the "Company"), and Steven G. Simonson, M.D. ("Executive"), subject to the terms and conditions defined in this Agreement.

WHEREAS, the Company and Executive desire that Executive be employed by the Company to act as the Company's Senior Vice President and Chief Development Officer, subject to the terms and conditions set forth in this Agreement. Executive's employment shall also be subject to such policies and procedures as the Company may from time to time implement;

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and Executive hereby agree as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through March 31, 2015; provided, however, that commencing on April 1, 2015 and on each April 1 thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such renewal date, either party shall have given notice that such party does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions hereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the expiration date of the then-current Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination. On the Date of Termination, Executive hereby resigns all employment and related job duties and responsibilities with the Company, including, without limitation any and all positions on any committees or boards of the Company or any affiliated company. Executive agrees to sign all documentation evidencing the foregoing as may be presented to Executive for signature by the Company.

3. Executive's Duties and Obligations.

(a) Duties. Executive shall serve as the Company's Senior Vice President and Chief Development Officer. Executive shall be responsible for all duties customarily associated with a Senior Vice President and Chief Development Officer in a publicly-traded company.

(b) Location of Employment. Executive's principal place of business shall be at the Company's headquarters to be located within thirty (30) miles of Warrington, Pennsylvania. In addition, Executive acknowledges and agrees that the performance by Executive of Executive's duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Matters. In consideration of the covenants contained herein, Executive has executed and agrees to be bound by the Company's standard form of Proprietary Information and Inventions, Non-Solicitation and Non-Competition Agreement (the "Confidentiality Agreement"), a form of which is attached to this Agreement as Exhibit B. Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During Executive's employment with the Company, Executive shall devote substantially all of Executive's time, attention and efforts to the proper performance of Executive's implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During Executive's employment with the Company, Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board of Directors of the Company (the "Board").

(c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity compete with the Company in the business of developing or commercializing (i) pulmonary surfactants or any other category of compounds which form the basis of the Company's material drug products, or (ii) any material medical device products under development by the Company, including without limitation the Company's capillary aerosol generator, series of aerosol-conducting airway connectors and related componentry, and similar medical devices; in each case, as determined in good faith by the Board on the Date of Termination. During the Term and for 18 months from the Date of Termination, Executive shall not solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the six (6) months preceding the Date of Termination; provided, that nothing herein shall prevent Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of Executive or (ii) if such discussions shall be held as a result of, or any employment shall be the result of, the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor.

(d) Injunctive Relief. In the event that Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(c) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to Executive (i) base annual compensation ("Base Salary"), effective as of December 19, 2014, of \$300,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the Company. Executive's Base Salary shall not be subject to reduction from the level in effect hereunder from time to time, other than pursuant to a salary reduction program of general application to contract executives of the Company.

(b) Bonuses. During the Term, Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, based upon a target Annual Bonus Amount of 30% of Base Salary, as may be awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of a similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives of a similar level or to other employees (including, without limitation, profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. If a conflict should exist between similar benefits afforded under any Company policy and the benefits afforded under this Agreement, the Company policy shall control, except to the extent that this Agreement shall provide for greater benefits, in which event the terms of this Agreement shall control. Anything contained herein to the contrary notwithstanding, throughout the Term, Executive shall be entitled to receive life insurance on behalf of Executive's named beneficiaries in an amount equal to the lesser of (i) Executive's then current annual salary for the Term of this Agreement and (ii) if less, the maximum amount available under the Company's insurance program, at no cost to Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such insurance.

(d) Vacations. During the Term, Executive shall be entitled to 20 days paid vacation per year, or such greater amount as may be earned under the Company's standard vacation policy, to be earned ratably throughout the year. Vacation days may be carried from one year to the next in accordance with the Company vacation policy.

(e) Reimbursement of Business Expenses. Executive is authorized to incur reasonable expenses in carrying out Executive's duties and responsibilities under this Agreement and the Company shall reimburse Executive for all such expenses, in accordance with reasonable policies of the Company.

6. Change of Control Benefits.

(a) Bonus. Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period that is at least equal to the Annual Bonus Amount; provided, that Executive is employed on the last day of such fiscal year. Such bonuses will be paid no later than the 15th day of the third month following the end of such fiscal year.

(b) Options. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested and, with respect to restricted stock, all restrictions shall be lifted upon the Change of Control Date. In the case of any Change of Control in which holders of the Company's common stock receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) Executive shall be permitted to exercise Executive's options at a time and in a fashion that will entitle Executive to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by Executive without Good Reason, Death or Disability.

(i) In the event of a termination of Executive's employment by the Company for Cause, a termination by Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of Executive, Executive shall be entitled to any unpaid compensation accrued through the last day of Executive's employment, a lump sum payment in respect of all accrued but unused vacation days at Executive's Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to Executive but not yet paid, less any amounts owed by Executive to the Company. Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or Disability, notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms.

(b) Termination by the Company without Cause or by Executive for Good Reason. If (x) Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) Executive terminates employment with Good Reason, then Executive will receive the amounts set forth in Section 7(a)(i) and, on the condition that the Executive signs a separation agreement containing a plenary release of claims in a form acceptable to the Company within fifty (50) days after the Date of Termination (or such shorter period specified in such plenary release) and such plenary release becomes final, binding and irrevocable, the Executive shall also be entitled to receive the following from the Company:

(i) A pro rata bonus equal to the Executive's Annual Bonus Amount (A) multiplied by the fraction obtained by dividing the aggregate amount of actual bonuses paid to the Company's other employment contract executives for the year that includes the Date of Termination by such employment contract executives' aggregate target bonuses for the year that includes the Date of Termination, multiplied by (B) the fraction obtained by dividing the number of days in the year through the Date of Termination by 365, which amount shall be paid when the Company's other employment contract executives are paid;

(ii) An amount equal to one (1) times the sum of (A) Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Annual Bonus Amount, payable in equal installments in accordance with the Company's regular payroll schedule, from the Date of Termination to the date that is 12 months after the Date of Termination (the "Severance Period") provided, however, that each installment payable before the plenary release becomes final, binding and irrevocable shall not be paid to the Executive until such plenary release becomes final, binding and irrevocable;

(iii) During the Severance Period, if Executive elects to continue Company medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Company shall continue to pay the Company's costs of such benefits as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company. If for any reason COBRA coverage is unavailable at any time during the Severance Period, the Company shall reimburse Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for Executive to purchase medical and dental coverage for Executive and Executive's dependents that is substantially equivalent to the medical and dental coverage that Executive and Executive's dependents were receiving immediately prior to the Date of Termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under the Company's plans. Company's obligation under this Section 7(b)(iii) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(iv) Upon the date that the plenary release becomes final, binding and irrevocable, notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and the Executive, all vested stock options to acquire Company stock and all other similar equity awards held by the Executive as of the Date of Termination shall continue to be exercisable during the Severance Period; and

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company.

Notwithstanding the foregoing, if Executive engages in a material breach of any provision of this Agreement or the Executive's Confidentiality Agreement during the Severance Period, and such breach is not cured within five business days after receipt from the Company of notice thereof, then the Company's continuing obligations under this Section 7(b) shall cease as of the date of the breach and the Executive shall be entitled to no further payments hereunder.

(c) Termination in connection with a Change of Control. If Executive's employment is terminated by the Company other than for Cause or by Executive for Good Reason during the Effective Period, then Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Annual Bonus Amount multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to 1.5 times the sum of (A) Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Annual Bonus Amount; provided, however, that if Executive's employment is terminated prior to the consummation of a Change of Control but under circumstances that would cause the Change of Control Date to precede the date that the Change of Control is consummated, such amount will be paid in equal installments in accordance with the Company's regular payroll schedule over the Severance Period described in Section 7(b)(ii);

(iv) If Executive elects to continue Company medical benefits under COBRA, for a period of 18 months following the Date of Termination (the "Benefit Period"), the Company shall continue to pay the Company's costs of such benefits as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company. If for any reason COBRA coverage is unavailable at any time during the Benefit Period, the Company shall reimburse Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for Executive to purchase medical and dental coverage for Executive and Executive's dependents that is substantially equivalent to the medical and dental coverage that Executive and Executive's dependents were receiving immediately prior to the Date of Termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under the Company's plans. Company's obligation under this Section 7(b)(iii) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms; and

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company.

Notwithstanding the foregoing, if Executive engages in a material breach of any provision of this Agreement or Executive's Confidentiality Agreement during the Severance Period, and such breach is not cured within five business days after receipt from the Company of notice thereof, then the Company's continuing obligations under this Section 7(c) shall cease as of the date of the breach and the Executive shall be entitled to no further payments or benefits hereunder.

8. Notice of Termination.

(a) Any termination of Executive's employment by the Company for Cause, or by Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination (at least 30 days in the case of Notice of Termination given by Executive for Good Reason), (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of Executive will not be deemed to be for Good Reason unless Executive gives the Notice of Termination provided for herein within 12 months after Executive has actual knowledge of the act or omission of the Company constituting such Good Reason and Executive gives the Company a 30 day cure period to rectify or correct the condition or event that constitutes Good Reason.

9. Mitigation of Damages. Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by Executive as the result of self-employment or employment by another employer or otherwise.

10. Excess Parachute Excise Tax.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), the Company will automatically reduce such Payments to the extent, but only to the extent, necessary so that no portion of the remaining Payments will be subject to the Excise Tax, unless the amount of such Payments that the Executive would retain after payment of the Excise Tax and all applicable Federal, state and local income taxes without such reduction would exceed the amount of such Payments that the Executive would retain after payment of all applicable Federal, state and local taxes after applying such reduction. Unless otherwise elected by the Executive, to the extent permitted under Code Section 409A, such reduction shall first be applied to any stock options, restricted stock or any other form of equity compensation (Equity Compensation") that is subject to exercise at a price per share that exceeds the closing price of the Company's common stock on the trading day immediately preceding the Change of Control, and thereafter pro rata among (i) severance payments payable to the Executive under this Agreement in reverse order of receipt, (ii) any remaining compensation in respect of Equity Compensation provided under this Agreement, starting with those options with the smallest spread between fair market value and exercise price first, and any restricted stock or restricted stock units, and (iii) any compensation related to continuation of benefits in reverse order of receipt.

(b) All determinations required to be made under this Section 10, including the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and Executive within 15 business days of the receipt of notice from Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. If the Accounting Firm determines that no Excise Tax is payable by Executive, it shall furnish Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and Executive.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

if to the Board or the Company:

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976
Attn: General Counsel

if to Executive:

The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this Agreement or any dispute or claim between Executive and the Company or its officers, directors, agents, or employees (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand." Such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The Dispute shall be resolved by a single arbitrator in an arbitration administered by the American Arbitration Association in accordance with its Employment Arbitration Rules and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The decision of the arbitrator shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrator may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Employment Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrator shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrator, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrator hereunder.

(iii) The arbitrator shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory and punitive damages if authorized by applicable law.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section 16(d) in the case of the Company, or to the Beneficiary in the case of the death of Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge Executive with or without Cause.

18. Section 409A of the Code. The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from, Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be construed and interpreted in accordance with such intent. Executive's termination of employment (or words to similar effect) shall not be deemed to have occurred for purposes of this Agreement unless such termination of employment constitutes a "separation from service" within the meaning of Code Section 409A and the regulations and other guidance promulgated thereunder.

(a) Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed on the date of Executive's termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B) and using the identification methodology selected by the Company from time to time, or if none, the default methodology set forth in Code Section 409A, then with regard to any payment or the providing of any benefit that constitutes "non-qualified deferred compensation" pursuant to Code Section 409A and the regulations issued thereunder that is payable due to Executive's separation from service, to the extent required to be delayed in compliance with Code Section 409A(a)(2)(B), such payment or benefit shall not be made or provided to Executive prior to the earlier of (i) the expiration of the six (6) month period measured from the date of Executive's separation from service, and (ii) the date of Executive's death (the "Delay Period"). On the first day of the seventh month following the date of Executive's separation from service or, if earlier, on the date of Executive's death, all payments delayed pursuant to this Section 18(a) shall be paid or reimbursed to Executive in a lump sum, and any remaining payments and benefits due to Executive under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(b) To the extent any reimbursement of costs and expenses provided for under this Agreement constitutes taxable income to Executive for Federal income tax purposes, such reimbursements shall be made no later than December 31 of the calendar year next following the calendar year in which the expenses to be reimbursed are incurred. With regard to any provision herein that provides for reimbursement of expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year. Any tax gross-ups provided for under this Agreement shall in no event be paid to Executive later than the December 31 of the calendar year following the calendar year in which the taxes subject to gross-up are incurred or paid by Executive.

(c) If any amount under this Agreement is to be paid in two or more installments, for purposes of Code Section 409A each installment shall be treated as a separate payment.

19. Executive Acknowledgement. Executive hereby acknowledges that Executive has read and understands the provisions of this Agreement, that Executive has been given the opportunity for Executive's legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that Executive has received a copy of this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Employment Agreement to be executed as of the date first above written.

Discovery Laboratories, Inc.

By: /s/ Kathryn A. Cole
Name: Kathryn A. Cole
Title: Senior Vice President, Human Resources

/s/ Steven G. Simonson
Steven G. Simonson, M.D.

EXHIBIT A

(a) **“Annual Bonus Amount”** means the current year’s target annual bonus amount for the Executive.

(b) **“Beneficiary”** means any individual, trust or other entity named by Executive to receive the payments and benefits payable hereunder in the event of the death of Executive. Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by Executive, or if no designated Beneficiary survives Executive, then the payment and benefits provided under this Agreement, if any, will be paid to Executive’s estate, which shall be deemed to be Executive’s Beneficiary.

(c) **“Cause”** means: (i) Executive’s willful and continued neglect of Executive’s duties with the Company (other than as a result of Executive’s incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to Executive by the Company which specifically identifies the manner in which the Company believes that Executive has neglected his duties; (ii) the final conviction of Executive of, or an entering of a guilty plea or a plea of no contest by Executive to, a felony; or (iii) Executive’s willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of Executive shall be considered “willful” unless it is done, or omitted to be done, by Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board, or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interests of the Company.

(d) **“Change of Control”** means the occurrence of any one of the following events:

(i) any “person” (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the “Exchange Act”), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly (x) acquires “beneficial ownership” (as defined in Rule 13d-3 under the Exchange Act) of securities representing more than 50% of the combined voting power of the Company’s then outstanding securities or; (y) acquires within a 12 consecutive month period “beneficial ownership” (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company’s then outstanding securities;

(ii) persons who comprise a majority of the Board are replaced during any 12 consecutive month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of such appointment or election;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a “Business Combination”) other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company’s voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, 50% or more of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company’s assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company’s voting securities immediately prior to such Business Combination; or

(iv) any “person” (as defined in Sections 13(d) and 14(d) of the Exchange Act) acquires all or substantially all of the assets of the Company within any 12 consecutive month period.

Notwithstanding the foregoing, none of the foregoing events shall constitute a Change of Control of the Company unless such event also constitutes a change in ownership of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(v), a change in the effective control of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(vi) or a change in ownership of a substantial portion of the assets of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(vii).

(e) “**Change of Control Date**” means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if Executive’s employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(f) “**Code**” means the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

(g) “**Date of Termination**” means the date specified in a Notice of Termination pursuant to Section 8 hereof, or Executive’s last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(h) “**Disability**” means a mental or physical condition that renders Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give Executive at least 30 days’ written notice that it considers the time period for disability to be running.

(i) **“Effective Period”** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.

(j) **“Good Reason”** means, unless Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to Executive of any duties materially inconsistent with Executive’s position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a material reduction in Executive’s Base Salary by the Company; (iii) the relocation of Executive’s office to a location more than 30 miles from Warrington, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); or (v) the failure of the Company to obtain the assumption in writing of the Company’s obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

EXHIBIT B

**FORM OF
PROPRIETARY INFORMATION AND INVENTIONS,
NON-SOLICITATION AND
NON-COMPETITION AGREEMENT**

The following is an agreement ("Agreement") between Discovery Laboratories, Inc., a Delaware corporation (the "Company"), and any successor in interest, and me, [Executive], and this Agreement is a material part of the consideration for my employment by the Company:

1. Job Title and Responsibility. I understand that my job title with the Company will be Senior Vice President and Chief Development Officer and that the Company may change this title at any time. My job duties and responsibilities will be those assigned to me by the Company from time to time.
 2. Consideration. I understand that the consideration to me for entering into this Agreement is my employment with the Company at my base salary of \$300,000, and I agree that this consideration is fully adequate to support this Agreement.
 3. Proprietary Information. I recognize that the Company is engaged in a continuous program of research, development and production. I also recognize that the Company possesses or has rights to secret, private, confidential information and processes (including processes and information developed by me during my employment by the Company) which are valuable, special and unique assets of the Company and which have commercial value in the Company's business ("Proprietary Information"). By way of illustration, this Proprietary Information includes, but is not limited to, information and details regarding the Company's business, trade or business secrets, inventions, intellectual property, systems, policies, records, reports, manuals, documentation, models, data and data bases, products, processes, operating systems, manufacturing techniques, research and development techniques and processes, devices, methods, formulas, compositions, compounds, projects, developments, plans, research, financial data, personnel data, internal business information, strategic and staffing plans and practices, business, marketing, promotional or sales plans, practices or programs, training practices and programs, costs, rates and pricing structures and business methods, computer programs and software, customer and supplier identities, information and lists, confidential information regarding customers and suppliers, and contacts at or knowledge of Company suppliers and customers or of prospective or potential customers of the Company.
 4. Obligation of Confidentiality. I understand and agree that my employment creates a relationship of confidence and trust between the Company and me with respect to (i) all Proprietary Information, and (ii) the confidential information of others with which the Company has a business relationship. At all times, both during my employment by the Company and after the termination of my employment (whether voluntary or involuntary), I will keep in confidence and trust all such information, and I will not use, reveal, communicate, or disclose any such Proprietary Information or confidential information to anyone or any entity, without the written consent of the Company, unless I am ordered to make disclosure by a court of competent jurisdiction.
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5. Ownership, Disclosure and Assignment of Proprietary Information and Inventions. In addition, I hereby agree as follows:

(a) Ownership and Assignment. All Proprietary Information is, and shall be, the sole and exclusive property of the Company and its assigns, and the Company and its assigns shall be the sole and exclusive owner of all Proprietary Information, including, but not limited to, trade secrets, inventions, patents, trademarks, copyrights, and all other rights in connection with such Proprietary Information. I agree that I have no rights in such Proprietary Information. I hereby assign, and shall assign, to the Company and its assigns any and all rights, title and interest I may have or acquire in such Proprietary Information. Any copyrightable work prepared in whole or in part by me in the course of my employment shall be deemed "a work made for hire" under applicable copyright laws, and the Company and its assigns shall own all of the rights in any copyright.

(b) Return of Materials and Property. All documents, records, apparatus, equipment, data bases, data and information stored in computers or on electronic disks, and other electronic, computer, intellectual, and physical property ("Materials and Property"), whether or not pertaining to Proprietary Information, furnished to me by the Company or produced by me or others in connection with employment, shall be and remain the sole and exclusive property of the Company. I shall return to the Company all such Materials and Property as and when requested by the Company. Even if the Company does not so request, I shall return all such Materials and Property upon termination of employment by me or by the Company for any reason, and I will not take with me any such Materials or Property, or any reproduction thereof, upon such termination.

(c) Notification. During the term of my employment and for one (1) year thereafter, I will promptly disclose to the Company, or any persons designated by it, all improvements, inventions, intellectual property, works of authorship, formulas, ideas, processes, techniques, discoveries, developments, designs, innovations, know-how and data, and creative works in which copyright and/or unregistered design rights will subsist in various media (all collectively called herein, "Inventions"), whether or not such Inventions are patentable, which I make or conceive, contribute to, reduce to practice, or learn, either alone or jointly with others.

(d) Ownership of Inventions. I agree and acknowledge that all Inventions which I make, conceive, develop, or reduce to practice (in whole or in part, either alone or jointly with others) at any time during my employment by the Company, and (i) which were created using the equipment, supplies, facilities or trade secret information of the Company, or (ii) which were developed during the hours for which I was compensated by the Company, or (iii) which relate, at the time of conception, creation, development or reduction to practice, to the business of the Company or to its actual or demonstrably anticipated research and development, or (iv) which result from any work performed by me for the Company, shall be the sole and exclusive property of the Company and its assigns (and to the fullest extent permitted by law shall be deemed works made for hire), and the Company and its assigns shall be the sole and exclusive owner of all Inventions, patents, copyrights and all other rights in connection therewith. I hereby assign to the Company any and all rights I may have or acquire in such Inventions. I agree that any Invention required to be disclosed under paragraph (c), above, within one (1) year after the termination of my employment shall be presumed to have been conceived or made during my employment with the Company and will be assigned to the Company unless and until I prove and establish to the contrary.

(e) Assistance and Cooperation. With respect to Inventions described in paragraph (d), above, I will assist the Company in every proper way (but at the Company's expense) to obtain, and from time to time enforce, patents, copyrights or other rights on these Inventions in any and all countries, and will execute all documents reasonably necessary or appropriate for this purpose. This obligation shall survive the termination of my employment. In the event that the Company is unable for any reason whatsoever to secure my signature to any document reasonably necessary or appropriate for any of the foregoing purposes (including renewals, extensions, continuations, divisions or continuations in part), I hereby irrevocably designate and appoint the Company, and its duly authorized officers and agents, as my agents and attorneys-in-fact to act for and in my behalf and instead of me, but only for the purpose of executing and filing any such document and doing all other lawfully permitted acts to accomplish the foregoing purposes with the same legal force and effect as if executed by me.

(f) Exempt Inventions. I understand that this Agreement does not require assignment of an Invention for which no equipment, supplies, facilities, resources, or trade secret information of the Company was used and which was developed entirely by me on my own time, unless the invention relates, (i) directly to the business of the Company, or (ii) to the Company's actual or demonstrably anticipated research or development. However, I will disclose to the Company any Inventions I claim are exempt, as required by paragraph (c), above, in order to permit the Company to determine such issues as may arise. Such disclosure shall be received in confidence by the Company.

6. Prior Inventions. As a matter of record I attach hereto as Exhibit A a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company which have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment with the Company, that I desire to remove from the operation of this Agreement, and I covenant that such list is complete. If no such list is attached to this Agreement, I represent that I have no such inventions and improvements at the time of my signing this Agreement.

7. Other Business Activities. So that the Company may be aware of the extent of any other demands upon my time and attention, I will disclose to the Company (such disclosure to be held in confidence by the Company) the nature and scope of any other business activity in which I am or become engaged during the term of my employment. During the term of my employment, I will not engage in any business activity or employment which is in competition with, or is related to, the Company's business or its actual or demonstrably anticipated research and development, or that will affect in any manner my ability to perform fully all of my duties and responsibilities for the Company.

8. Non-Interference and Non-Solicitation of Employees, Customers and Others. I will not now or at any time in the future disrupt, damage, impair or interfere with the business of the Company, whether by way of interfering with or raiding its employees, disrupting its relationships with customers, agents, vendors, distributors or representatives, or otherwise. During my employment with the Company and for eighteen (18) months thereafter, I will not directly or indirectly induce, encourage or solicit any employee of the Company to leave the Company for any reason, unless specifically requested to take such action in writing by the Company.

9. Non-Competition During and After Employment. I agree that the time and activity restrictions in this paragraph are wholly necessary and are reasonable to protect the legitimate business interests of the Company. During my employment with the Company or at any time within a period of one (1) year after the termination of my employment (whether the termination is by me or the Company), I will not directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity, compete with the Company in the business of developing or commercializing pulmonary surfactants.

10. Obligations to Former Employers. I represent that my execution of this Agreement, my employment with the Company, and my performance of my duties and proposed duties to the Company will not violate any obligations or agreements I have, or may have, with any former employer or any other third party, including any obligations and agreements requiring me not to compete or to keep confidential any proprietary or confidential information. I have not entered into, and I will not enter into, any agreement which conflicts with this Agreement or that would, if performed by me, cause me to breach this Agreement. I further represent that I have no knowledge of any pending or threatened litigation to which the Company may become a party by virtue of my association with the Company. I further agree to immediately inform the Company of any such pending or threatened litigation should it come to my attention during the course of my employment. I also agree that I provided to the Company for its inspection before I signed this Agreement all confidentiality, non-compete, non-solicitation, and all other employment-related agreements that I am party to or which involve me.

11. Confidential Information of, and Agreements with, Former Employers. In the course of performing my duties to the Company, I will not utilize any trade secrets, proprietary or confidential information of or regarding any former employer or business affiliate, nor violate any written or oral, express or implied agreement with any former employer or business affiliate.

12. United States Government Obligations. I acknowledge that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to be bound by all such obligations and restrictions which are made known to me and to take all action necessary to discharge the obligations of the Company under such agreements.

13. Remedies. I acknowledge that my failure to comply with, or my breach of, any of the terms and conditions of this Agreement shall irreparably harm the Company, and that money damages would not adequately compensate the Company for this harm. Accordingly, I acknowledge that in the event of a threatened or actual breach by me of any provision of this Agreement, in addition to any other remedies the Company may have at law, the Company shall be entitled to equitable relief in the form of specific performance, temporary restraining order, temporary or permanent injunction or any other equitable remedy then available, without requiring the Company to post any bond. I agree that nothing herein contained shall be construed as prohibiting the Company from pursuing any other remedies available to it for such threatened or actual breach, including money damages, and I agree that the Company shall be entitled to recover from me any attorney's fees it incurs in enforcing the terms of this Agreement.

14. Not an Employment Agreement. I acknowledge and agree that this Agreement is not a contract of employment, that it should not be construed as a guarantee of my employment for any period of time, and that I am employed by the Company at will and my employment may be terminated by the Company for any lawful reason or no reason.

15. Miscellaneous.

(a) Reformation and Severability. If any provision of this Agreement is held to be invalid or unenforceable under applicable law, such provision shall be reformed and/or construed, if possible, to be enforceable under applicable law; otherwise, such provision shall be excluded from this Agreement and the balance of the Agreement shall remain fully enforceable and valid in accordance with its terms.

(b) No Waiver. No delay or omission by the Company in exercising any right hereunder will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(c) Reassignment. I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employment I may be transferred, without the necessity that this Agreement be reassigned at the time of such transfer.

(d) Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania (but not the law or principles of conflict of laws), and the parties submit to the jurisdiction of the courts of Pennsylvania.

(e) Effective Date. This Agreement shall be effective as of the first day of my employment by the Company, shall be binding upon me, my heirs, executors, assigns and administrators, and shall inure to the benefit of the Company, its successors and assigns.

(f) Entire Agreement. This Agreement contains the entire agreement of the parties relating to the subject matter herein, and may not be waived, changed, extended or discharged except by an agreement in writing signed by both parties.

(g) ACKNOWLEDGEMENT. I acknowledge and agree that I have fully read and that I understand all of the terms and provisions of this Agreement, that I have had the opportunity to consult with an attorney and to discuss this Agreement with an attorney, that I have had any questions regarding the effect of this Agreement or the meaning of its terms answered to my satisfaction, and, intending to be legally bound hereby, I freely and voluntarily sign this Agreement.

Accepted and Agreed to:

DISCOVERY LABORATORIES, INC.

Name: _____
Date: _____
SS#: _____

By: _____
Name: _____
Title: _____

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976

Attn:

1. The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by Discovery Laboratories, Inc. (the "Company") that have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment by the Company that I desire to remove from the operation of the Company's Proprietary Information and Inventions, Non-Solicitation and Non-Competition Agreement.

_____ No inventions or improvements

_____ See below: Any and all inventions regarding

_____ Additional sheets attached.

2. I propose to bring to my employment the following materials and documents of a former employer:

_____ No materials or documents.

_____ See below:

Date

December 29, 2014

Steven G. Simonson, M.D.
c/o Discovery Laboratories, Inc.
2600 Kelly Road
Suite 100
Warrington, PA 18976

Re: Amendment to Employment Agreement

Dear Dr. Simonson,

This amendment is attached to and made part of the Employment Agreement dated as of December 29, 2014 between you and Discovery Laboratories, Inc. (the "Agreement"). Effective as of April 1, 2015, the parties hereby agree that certain provisions of the Agreement are revised as set forth below. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Agreement.

1. The first sentence of Section 2 is hereby amended and restated in its entirety to read as follows:

"The term ("Term") of this Agreement shall commence on the date first above written and shall continue through March 31, 2015; provided, however, that commencing on April 1, 2015 and on each renewal date thereafter, the term of this Agreement shall automatically be extended for two additional years, unless at least 90 days prior to any such renewal date, either party shall have given notice that such party does not wish to extend this Agreement."

2. Section 6(b) of the Agreement ("Change of Control Benefits – Options") is hereby amended and restated in its entirety to read as follows:

"Awards. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock award between the Company and Executive, in the event of a Change of Control, all vested and unvested shares of stock and all vested and unvested options to acquire Company stock held by Executive shall be assumed by the successor entity or parent or subsidiary of the successor entity; and further, if the Company is not the surviving entity, Executive shall be entitled to receive in exchange for, or in respect of, all shares of stock and all options in the Company's common stock, shares and options to acquire shares of the successor entity or parent or subsidiary of the successor entity, or other similar rights that are substantially the economic equivalent of the Executive's shares and stock options in the Company's common stock immediately prior to the Change of Control."

3. Clause (v) of Section 7(c) ("Termination of Employment – Termination in connection with a Change of Control") is hereby amended in its entirety to read as follows:

"Notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock (or shares and options to acquire shares of a successor entity or parent or subsidiary of the successor entity issued or substituted for shares and options to acquire Company stock pursuant to Section 6(b) hereof) held by Executive shall accelerate and become fully vested upon the Date of Termination (and shall thereupon become fully exercisable) and all shares of stock shall become fully vested upon the Date of Termination and all restrictions thereon shall be lifted, and all stock options shall continue to be exercisable for the remainder of their stated terms."

Except as amended herein, the remaining terms and conditions of the Agreement shall remain in full force and effect. This amendment confirms an agreement between you and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and mutual promises made in connection therewith. Please indicate your acceptance of the terms contained herein by signing both copies of this amendment, retaining one copy for your records, and forwarding the remaining copy to the Company no later than December 31, 2014.

DISCOVERY LABORATORIES, INC.

By: /s/ Kathryn A. Cole
Name: Kathryn A. Cole
Title: Senior Vice President, Human Resources

Accepted and Agreed to:

/s/ Steven G. Simonson
Name: Steven G. Simonson, M.D.

Date: December 31, 2014

AMENDMENT TO RESEARCH AND DEVELOPMENT SERVICES AGREEMENT

Effective as of May 7, 2015, Battelle Memorial Institute and Discovery Laboratories, Inc. hereby agree to amend the Research and Development Services Agreement between them dated as of June 22, 2012 (as it may have been previously amended, the "Agreement") to reflect the revisions set forth herein. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Agreement.

1. Section 1., Term, Acceptance of Proposal(s), of the Agreement is hereby amended and restated in its entirety to read as follows:

"The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until June 31, 2016 unless earlier terminated as provided in Section 11. Discovery's acceptance of Battelle's Proposal(s) and the commencement and timeline of services thereunder shall be as set forth in the respective Proposal(s)."

Except as amended herein, the remaining terms and conditions of the Agreement shall remain in full force and effect. This Amendment to Research and Development Services Agreement confirms an agreement between Battelle Memorial Institute and Discovery Laboratories, Inc. with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and mutual promises made in connection therewith. The parties have executed this Amendment to Research and Development Services Agreement on the day and date first set forth above.

Battelle Memorial Institute
Corporate Operations

Discovery Laboratories, Inc.

By: /s/ Beth A. Gustin
Name: Beth A. Gustin
Title: Sr. Contracts Officer

By: /s/ Mary B. Templeton
Name: Mary B. Templeton, Esq.
Title: SVP, General Counsel

CERTIFICATIONS

I, John G. Cooper, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Discovery Laboratories, Inc. (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: May 11, 2015

/s/ John G. Cooper

John G. Cooper
President and Chief Executive Officer

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: May 11, 2015

/s/John A. Tattory

John A. Tattory

Senior Vice President and Chief Financial Officer

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended March 31, 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: May 11, 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.
