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

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2014
or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

As of October 31, 2014, 85,337,466 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

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PART II - OTHER INFORMATION

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

FORWARD-LOOKING STATEMENTS

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

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

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

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

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

- the risk that the initial and later phases of our AEROSURF clinical program may be interrupted, delayed, or fail, which will harm our business;

- the risk that we may not succeed in implementing our long-term manufacturing strategy to assure continuity of SURFAXIN commercial drug product supply, which may affect our ability to maintain sufficient supplies of SURFAXIN commercial drug product;

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

- the risk that 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;

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

- risks relating to our and our CMOs' ability to manufacture our KL4 surfactant, in liquid and lyophilized dosage forms, which require precise methods of manufacture in an aseptic manufacturing environment, as well as complex analytical and quality control release and stability methodologies, for both commercial and research and development activities;

- risks relating to our and our CMOs' ability to develop and manufacture combination drug/device products based on our CAG technology, for preclinical and clinical studies of our product candidates and, ultimately if approved, for commercialization;

- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems in manufacturing our KL4 surfactant drug products and the APIs used in the manufacture of our drug products, CAG devices and other materials on a timely basis or in an amount sufficient to support our needs;

- risks relating to our plans to potentially secure marketing and distribution capabilities in certain markets through third-party strategic alliances and/or marketing alliances and/or distribution arrangements, that could require us to give up rights to our drug products, drug product candidates and drug delivery technologies;

- the risk that we may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us in markets outside the U.S. with the development of our KL4 surfactant pipeline products, beginning with AEROSURF, including development of our lyophilized KL4 surfactant, and, if approved, commercialization of AEROSURF in markets outside the U.S.; support the commercialization of SURFAXIN in countries where regulatory approval is facilitated by the information contained in the SURFAXIN new drug application (NDA) approved by the FDA; and potentially support the development and, if approved, commercialization, of our other pipeline products;

- risks relating to our pledge of substantially all of our assets to secure our obligations under our loan facility (Deerfield Loan) with affiliates of Deerfield Management Company, L.P., which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investment; and

- other risks and uncertainties as detailed in "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 17, 2014, and our other filings with the SEC and any amendments thereto, and in the documents incorporated by reference in this report.

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

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

Trademark Notice

AEROSURF®, AFECTAIR®, DISCOVERYLABS®, INSPIRED INNOVATION®, SURFAXIN® and **WARMING CRADLE®** are registered trademarks and SURFAXIN LS™ is a common law trademark 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)

	September 30, 2014 (Unaudited)	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 54,915	$ 86,283
Accounts receivable	22	67
Inventory, net	429	112
Prepaid expenses and other current assets	357	777
Total current assets	55,723	87,239
Property and equipment, net	1,772	1,656
Restricted cash	325	325
Other assets	489	97
Total assets	$ 58,309	$ 89,317
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,403	$ 1,433
Accrued expenses	4,804	4,785
Deferred revenue	95	139
Common stock warrant liability	3,049	5,425
Equipment loans, current portion	76	73
Total current liabilities	9,427	11,855
Long-term debt, $30,000 net of discount of $10,232 at September 30, 2014 and $11,646 at December 31, 2013	19,768	18,354
Equipment loans, non-current portion	7	69
Other liabilities	142	538
Total liabilities	29,344	30,816
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 250,000,000 and 150,000,000 shares authorized at September 30, 2014 and December 31, 2013, respectively; 85,358,358 and 84,659,111 shares issued at September 30, 2014 and December 31, 2013, respectively; 85,337,466 and 84,638,219 shares outstanding at September 30, 2014 and December 31, 2013, respectively	85	85
Additional paid-in capital	545,307	541,420
Accumulated deficit	(513,373)	(479,950)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total stockholders' equity	28,965	58,501
Total liabilities & stockholders' equity	$ 58,309	$ 89,317

See notes to consolidated financial statements.

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

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Product sales	$ 106	$ –	$ 176	$ –
Grant revenue	421	60	1,475	315
	527	60	1,651	315
Expenses:				
Cost of product sales	257	–	1,769	–
Research and development	6,471	6,574	18,919	21,909
Selling, general and administrative	4,126	4,299	12,995	12,648
	10,854	10,873	33,683	34,557
Operating loss	(10,327)	(10,813)	(32,032)	(34,242)
Change in fair value of common stock warrant liability	173	(1,059)	1,999	1,627
Other income / (expense):				
Interest and other income	2	1	6	2
Interest and other expense	(1,172)	(353)	(3,396)	(873)
Other income / (expense), net	(1,170)	(352)	(3,390)	(871)
Net loss	$ (11,324)	$ (12,224)	$ (33,423)	$ (33,486)
Net loss per common share				
Basic	$ (0.13)	$ (0.22)	$ (0.39)	$ (0.68)
Diluted	$ (0.13)	$ (0.22)	$ (0.41)	$ (0.69)
Weighted average number of common shares outstanding				
Basic	85,209	54,792	85,001	49,235
Diluted	85,209	54,792	86,121	50,377

See notes to consolidated financial statements.

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

(in thousands)

	Nine Months Ended September 30,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (33,423)	$ (33,486)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	577	537
Provision for excess inventory	1,596	–
Stock-based compensation and 401(k) Plan employer match	3,053	2,367
Fair value adjustment of common stock warrants	(1,999)	(1,627)
Amortization of discount on long-term debt	1,414	302
Changes in:		
Inventory	(2,319)	78
Accounts receivable	45	–
Prepaid expenses and other current assets	420	301
Accounts payable	(30)	323
Accrued expenses	19	912
Deferred revenue	(44)	–
Other assets	–	(115)
Other liabilities	(396)	(12)
Net cash used in operating activities	(31,087)	(30,420)
Cash flows from investing activities:		
Purchase of property and equipment	(679)	(204)
Net cash used in investing activities	(679)	(204)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	–	15,114
Proceeds from issuance of long-term debt, net of expenses	–	9,850
Proceeds from exercise of common stock options	31	1
Proceeds from exercise of common stock warrants	426	–
Repayment of equipment loans	(59)	(56)
Net cash provided by financing activities	398	24,909
Net decrease in cash and cash equivalents	(31,368)	(5,715)
Cash and cash equivalents – beginning of period	86,283	26,892
Cash and cash equivalents – end of period	$ 54,915	$ 21,177
Supplementary disclosure of cash flows information:		
Interest paid	$ 1,968	$ 559

See notes to consolidated financial statements.

Notes to Consolidated Financial Statements (unaudited)

Note 1 – Organization and Business

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on creating life-saving products for critical-care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug technology produces a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies and devices potentially to enable efficient delivery of our aerosolized KL_4 surfactant. We believe that our proprietary technologies may make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

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

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

AEROSURF® is our investigational combination drug/device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). AEROSURF potentially will enable administration of aerosolized KL_4 surfactant to premature infants supported with nCPAP, without invasive intubation and mechanical ventilation. By enabling delivery of our KL_4 surfactant using less invasive procedures, we believe that AEROSURF may address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated. We are currently conducting a phase 2a clinical trial for AEROSURF for the treatment of RDS in premature infants, which, generally due to slow periods of enrollment, is now expected to conclude in the first quarter of 2015. We are also preparing for the phase 2b clinical trial and, in connection with that effort, have identified four new clinical sites that will be initiated in November 2014 to assist with completing enrollment in the phase 2a clinical trial. We expect that these eight sites will be able to apply the experience and knowledge being developed during the phase 2a program to assist with the transition to the next phase of the clinical program. Based on our recent assessment of our clinical plan, we now expect our phase 2b clinical trial to complete in the first half of 2016.

We are also developing a lyophilized (freeze-dried) dosage form of our KL_4 surfactant that is stored as a powder and reconstituted to liquid form prior to use with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are initially developing this dosage form for use in our AEROSURF development program. We are also engaged in discussions with the FDA to determine if we could gain marketing authorization for a lyophilized dosage form of our KL_4 surfactant under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the U.S. and potentially in other markets.

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

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

Note 2 – Liquidity Risks and Management's Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, and, more recently, commercialization and medical affairs activities, and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, debt facilities, strategic alliances, the use of committed equity financing facilities (CEFFs) and at-the-market (ATM) equity programs, and capital equipment financings.

As of September 30, 2014, we had cash and cash equivalents of $54.9 million and long-term debt of $30 million ($19.8 million net of discount) under our loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see,* Note 7, "– Deerfield Loan"). Before any additional financings, including under our ATM Program (*see*, Note 11 - "At-the-Market Program (ATM Program)," to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2013 (2013 Form 10-K)), we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the third quarter of 2015.

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

Our future capital requirements will depend upon many factors, primarily our efforts to (i) execute the commercial introduction of SURFAXIN in the U.S.; (ii) assure long-term continuity of supply for our commercial liquid, lyophilized and aerosolized KL_4 surfactant drug product, at our manufacturing facility in Totowa, NJ (Totowa Facility) and with CMOs, (iii) advance the AEROSURF development program to completion of the phase 2 clinical trials as planned; (iv) further the development of our CAG for use in a planned phase 3 clinical program and, if approved, early commercial activities, (v) prepare for and conduct an AEROSURF phase 3 clinical program; and (vi) secure one or more strategic alliances or other collaboration arrangements to support our development programs and commercialization of our approved products, if any, in markets outside the U.S. We believe that we will be better positioned to enter into a significant strategic alliance if we are successful in advancing the commercial introduction of SURFAXIN, and completing and obtaining encouraging results from the AEROSURF phase 2 clinical program within our anticipated time.

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

As of September 30, 2014, we had outstanding warrants to purchase approximately 14 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, warrants to purchase 7 million shares were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share (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 contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. These warrants currently have an exercise price of $1.50 per share and expire in February 2016. In addition, in October 2014, we issued to Battelle Memorial Institute (Battelle) warrants to purchase 1.5 million shares of our common stock at an exercise price of $5.00, with a 10-year term, exercisable upon achievement of a development milestone defined in the related Collaboration Agreement with Battelle of the same date, provided that the purchase of 0.5 million shares is subject to the further condition that the milestone be achieved on or before May 31, 2016. *See,* Note 9, "– Subsequent Event." Although we could receive additional capital from the exercise of any of our outstanding warrants for cash, there can be no assurance that the market price of our common stock will equal or exceed price levels that would make exercise of outstanding warrants likely, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

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

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

The preparation of financial statements, in conformity with accounting principles generally accepted in the United States, 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.

Inventory

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

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

Accrued Severance and Retention Costs

A liability for employee severance and retention benefits is recognized when (1) management has committed to a plan of termination; (2) the plan provides sufficient details, such as the employees affected, amounts to be paid, and expected dates of termination and payment; (3) it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn; and (4) the plan has been communicated to employees. The cost of such benefits 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. If we succeed in our efforts to secure longer-term utilization of the Totowa Facility, the severance plan and retention bonuses will remain in effect. The total cash amount expected to be paid for severance and retention under this plan through June 2016, assuming a June 2015 plant closing, is approximately $0.9 million. The plan-related expense for the three and nine months ended September 30, 2014 was $0.1 million and $0.3 million, respectively, and is included in research and development expense and cost of product sales. The related accrued liability is $0.5 million as of September 30, 2014.

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

Product Sales

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

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

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

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

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

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

- *Returns*. Sales of our products are not subject to a general right of return; however, we will accept product that is damaged or defective when shipped or for expired product up to six months subsequent to its expiry date.

Research and development expense

We track research and development expense by activity, as follows: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs. Research and development expense includes personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred.

Net loss per common share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period.

For the quarters ended September 30, 2014 and 2013, the number of shares of common stock potentially issuable upon the exercise of stock options and warrants was 20.8 million and 15.8 million shares, respectively. As of September 30, 2014 and 2013, 16.2 million and 10.7 million shares of common stock potentially issuable upon the exercise of stock options and warrants were excluded from the computation of diluted net loss per common share because their impact would have been anti-dilutive.

In accordance with Accounting Standards Codification (ASC) Topic 260, "*Earnings per Share,*" when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of 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 September 30, 2014 and 2013, the effect of the adjustments for warrants classified as derivative liabilities was anti-dilutive. For the nine months ended September 30, 2014 and 2013, the effect of the adjustments for warrants classified as derivative liabilities was dilutive.

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

(in thousands)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Numerator:				
Net loss as reported	$ (11,324)	$ (12,224)	$ (33,423)	$ (33,486)
Less: income from change in fair value of warrant liability	–	–	(1,993)	(1,525)
Numerator for diluted net loss per common share	$ (11,324)	$ (12,224)	$ (35,416)	$ (35,011)
Denominator:				
Basic weighted average common shares outstanding	85,209	54,792	85,001	49,235
Dilutive common shares from assumed warrant exercises	–	–	1,120	1,142
Diluted weighted average common shares outstanding	85,209	54,792	86,121	50,377

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

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. generally accepted accounting principles (GAAP) when it becomes effective. The new standard is effective for us in the annual period ending December 31, 2017, including interim periods within that annual period. Early application is not permitted. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements – Going Concern*, which requires management to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The standard defines substantial doubt as when it is probable (i.e., likely) that the entity will be unable to meet its obligations as they become due within one year of the date the financial statements are issued (or available to be issued, when applicable). The ASU is effective for the annual period ending December 31, 2016 and interim periods thereafter. Early application is permitted. We are evaluating the effect that ASU 2014-15 will have on our consolidated financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

Note 4 – Fair Value of Financial Instruments

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

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

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

Fair Value on a Recurring Basis

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

	Fair Value	Fair value measurement using		
	September 30, 2014	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 54,915	$ 54,915	$ –	$ –
Certificate of Deposit	325	325	–	–
Total Assets	$ 55,240	$ 55,240	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 3,049	$ –	$ –	$ 3,049

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

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

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2013	$ 5,425
Exercise of warrants	(377)
Change in fair value of common stock warrant liability	(1,999)
Balance at September 30, 2014	$ 3,049

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2012	$ 6,305
Change in fair value of common stock warrant liability	(1,627)
Balance at September 30, 2013	$ 4,678

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

Significant Unobservable Input Assumptions of Level 3 Valuations	September 30, 2014	December 31, 2013
Historical Volatility	46% – 57%	62% – 76%
Expected Term (in years)	0.4 – 1.4	0.4 – 2.1
Risk-free interest rate	0.03% – 0.31%	0.08% – 0.44%

Fair Value of Long-Term Debt

At September 30, 2014, the estimated fair value of the Deerfield Loan was $22.8 million compared to a carrying value, net of discounts, of $19.8 million. At December 31, 2013, the estimated fair value of the Deerfield Loan was $23.6 million compared to a carrying value, net of discounts, of $18.4 million. The estimated fair value of the Deerfield Loan was based on discounting the future contractual cash flows to the present value. This analysis utilizes certain Level 3 unobservable inputs, including current cost of capital. Considerable judgment is required to interpret market data and to develop estimates of fair value. The estimates presented are not necessarily indicative of amounts that could be realized in a current market exchange. The use of alternative market assumptions and estimation methodologies could have a material effect on these estimates of fair value.

Note 5 – Inventory

Inventory is comprised of the following for the periods presented:

(in thousands)	September 30, 2014	December 31, 2013
Inventories, current:		
Raw materials	$ 282	$ 52
Finished goods, net of reserves	147	60
	429	112
Inventories, non-current:		
Raw materials	406	–
Total inventories, net	$ 835	$ 112

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

In addition, as of September 30, 2014, we had $0.6 million of raw materials that were purchased prior to October 4, 2013, the date the FDA approved updated SURFAXIN product specifications and enabled the commercial introduction of SURFAXIN. These raw materials have a carrying value of zero, as the costs to purchase this material were expensed in the period of purchase as research and development expense, and accordingly are not reflected in the inventory balances shown above. These raw materials are anticipated to be used in manufacturing development, research and development activities and in the manufacture of commercial product.

Inventory reserves as of September 30, 2014 and December 31, 2013 were $2.1 million and $0.5 million, respectively. Inventory reserves reflect costs of SURFAXIN finished goods inventories that are not anticipated to be recoverable through the commercial sale of the product during the initial launch period due to product expiration. These reserves ensure that the inventory carrying values do not exceed net realizable value. Inventory reserves are recorded as a component of cost of goods sold.

Note 6 – Common Stock Warrant Liability

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

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

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

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

				Fair Value of Warrants *(in thousands)*		
Issuance Date	Number of Warrant Shares Issuable	Exercise Price	Warrant Expiration Date	Value at Issuance Date	September 30, 2014	December 31, 2013
5/13/2009	466,667	$ 17.25	5/13/2014	$ 3,360	$ –	$ –
2/23/2010	916,669	12.75	2/23/2015	5,701	–	6
2/22/2011	4,550,100	1.50	2/22/2016	8,004	3,049	5,419
					$ 3,049	$ 5,425

During the three and nine months ended September 30, 2014, holders of the February 2011 warrants exercised warrants to purchase 2,500 and 284,850 shares of common stock for total proceeds of $3,000 and $426,000, respectively. No warrants were exercised during the three and nine months ended September 30, 2013.

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

Note 7 – Deerfield Loan

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

(in thousands)	**September 30, 2014**	**December 31, 2013**
Note Payable	$ 30,000	$ 30,000
Unamortized discount	(10,232)	(11,646)
Long-term debt, net of discount	$ 19,768	$ 18,354

The principal amount of the loan is payable in three equal annual installments on the fourth, fifth and sixth anniversaries of the Deerfield Loan agreement beginning in February 2017, provided that the amount payable on the fourth anniversary shall be deferred for one year if either (i) "Net Sales" for the immediately preceding 12-month period are at least $20 million, or (ii) "Equity Value" is at least $200 million; and provided further, that the amount payable on the fifth anniversary (together with any amount deferred on the fourth anniversary) shall be deferred until the sixth anniversary if either (i) "Net Sales" for the immediately preceding 12-month period are at least $30 million, or (ii) "Equity Value" is at least $250 million. Accordingly, if the milestones are achieved in each year, payment of the principal amount could be deferred until the sixth anniversary date of the loan, February 13, 2019.

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Cash interest expense	$ 662	$ 221	$ 1,963	$ 551
Non-cash amortization of debt discounts	504	125	1,414	302
Amortization of debt costs	5	5	15	13
Total interest expense	$ 1,171	$ 351	$ 3,392	$ 866

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

In connection with the 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," to the consolidated financial statements in our 2013 Form 10-K.

Note 8 – Stock Options and Stock-Based Employee Compensation

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

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

	September 30,	
	2014	**2013**
Weighted average expected volatility	100%	110%
Weighted average expected term	5.4 years	4.7 years
Weighted average risk-free interest rate	1.65%	0.74%
Expected dividends	–	–

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Research & Development	$ 313	$ 210	$ 860	$ 551
Selling, General & Administrative	544	431	1,482	1,053
Total	$ 857	$ 641	$ 2,342	$ 1,604

Note 9 – Subsequent Event

We evaluated all events or transactions that occurred after September 30, 2014 up through the date we issued these financial statements. During this period, we noted one non-recognized subsequent events as described below:

On October 10, 2014, we entered into the Collaboration Agreement with Battelle providing for the further development of our CAG for potential use in our planned phase 3 clinical program for AEROSURF for the treatment of RDS in premature infants and, if AEROSURF is approved for commercial sale by the FDA or other regulatory authority, initial commercial supply.

Pursuant to the Collaboration Agreement, we and Battelle will work together to (i) define the requirements of the phase 3 CAG and disposable dose packs (together, AEROSURF System) and a detailed project plan for the project (Stage 1), (ii) develop the AEROSURF System in accordance with the project plan (Stage 2), and (iii) complete all required testing, verification and documentation to be in a position to manufacture AEROSURF Systems (Stage 3). Upon completion of the three-stage project plan, we and Battelle intend to negotiate in good faith to enter into an agreement for the manufacture of AEROSURF Systems for the AEROSURF phase 3 clinical program, and, if AEROSURF is approved, to negotiate in good faith to enter into a supply agreement providing for an initial commercial supply of AEROSURF Systems.

A Steering Committee, comprised of an equal number of members appointed by each party, will oversee the work of the project and attempt to reach consensus on the handling of all matters referred to it. The foregoing notwithstanding, we will retain final decision-making authority on all matters related to the design, registration, manufacture, packaging, marketing, distribution and sale of the AEROSURF Systems. We and Battelle will share equally in the costs of Stage 1 activities. Following completion of Stage 1, we and Battelle will agree on the details and projected costs for Stages 2 and 3. The parties will share equally in the costs of the project plan for Stages 2 and 3 as set forth in the project plan. Battelle will bear the entire cost of any cost overruns associated with execution of the project plan and we will bear the entire cost of any increase in the agreed upon project plan costs resulting from changes in the scope of the product requirements as agreed in Stage 1 and set forth in the project plan.

In connection with the Collaboration Agreement, on October 10, 2014, we issued to Battelle two warrants to purchase shares of our common stock, each having an exercise price of $5.00 per share and a term of 10 years, subject to earlier termination under certain circumstances set forth therein, including (i) a warrant to purchase up to 1.0 million shares of our common stock, exercisable upon successful completion by Battelle of the Stage 3 activities (Initial Warrant), and (ii) a warrant to purchase up to 0.5 million shares of our common stock (Additional Warrant; and together with the Initial Warrant, the Battelle Warrants), exercisable if and only if Battelle successfully completes the Stage 3 activities no later than May 31, 2016, which date may be adjusted as provided in the Collaboration Agreement. We and Battelle have agreed to execute a registration rights agreement providing for the registration of the resale of shares underlying the Battelle Warrants. The Battelle Warrants may be exercised for cash only, except that, in the event a registration statement is not effective at the time of exercise and if an exemption from registration is otherwise available at that time, the Battelle Warrants may be exercised on a cashless basis. The Battelle Warrants were issued pursuant to an exemption from registration contained in Regulation D, Rule 506.

In addition to the Battelle Warrants, if Battelle successfully completes the Stage 3 activities, we have agreed to pay Battelle royalties equal to a low single-digit percentage of the worldwide net sales and license royalties on sales of AEROSURF for the treatment of RDS in premature infants, up to an aggregate limit of $25 million.

The term of the Collaboration Agreement will end at the time we fulfill our payment obligations to Battelle, except that the Collaboration Agreement may be terminated by a party under certain circumstances, including (i) a declaration of bankruptcy by either party, (ii) a "failure of purpose" as defined in the Collaboration Agreement, including without limitation, a good faith determination by the parties that the objectives of the AEROSURF clinical program, the FDA registration of AEROSURF, or the expected outcomes of the project plan cannot be achieved, or (iii) a material breach by either party.

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

Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks and uncertainties. You should review the "Forward-Looking Statements" section, and the risk factors discussed in the "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, as well as in our Annual Report on Form 10-K for the year ended December 31, 2013 that we filed with the Securities and Exchange Commission (SEC) on March 17, 2014 (2013 Form 10-K) and our other filings with the SEC, and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.

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

OVERVIEW

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

We are initially focused on improving the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants. RDS is the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU) and can result in long-term respiratory problems, developmental delay and death. Our first 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) and has been commercially available in the U.S. since November 2013. SURFAXIN is our KL4 surfactant in liquid form, and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently available in the United States (U.S.).

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

AEROSURF® is our investigational combination drug/device product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG). AEROSURF potentially will enable administration of aerosolized KL4 surfactant to premature infants supported with nCPAP, without invasive intubation and mechanical ventilation. By enabling delivery of our KL4 surfactant using less invasive procedures, we believe that AEROSURF may address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

We are also developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that is stored as a powder and reconstituted to liquid form prior to use with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are initially developing this dosage form for use in our AEROSURF development program. We are also engaged in discussions with the FDA to determine if we could gain marketing authorization for a lyophilized dosage form of our KL4 surfactant under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the U.S. and potentially in other markets.

To support the commercial introduction of SURFAXIN in the U.S. and our other KL4 surfactant pipeline products, if approved, we have our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and is focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be able to efficiently introduce our other KL4 surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL4 surfactant. In addition, we recognize that our commercial and medical affairs team could potentially support introductions of other synergistic pipeline products, including products owned or developed by third parties for the NICU/PICU. To that end, in appropriate circumstances, we may consider potential transactions focused on securing commercial rights to such synergistic products, including in the form of product acquisitions, in-licensing agreements or distribution, marketing or co-marketing arrangements.

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

Business and Pipeline Programs Update

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business," in our 2013 Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and our current and planned KL4 pipeline programs.

Following are updates to our products and pipeline programs since the filing of our 2013 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. Our commercial and medical teams are working to secure formulary acceptance with hospitals that we believe to be recognized centers of excellence with strong reputations and regional and national influence in the neonatal community, as well as affiliated and regional hospitals. Although not an indicator or predictor of revenue, in most cases, formulary acceptance is a necessary prerequisite to be able to sell SURFAXIN drug product to a hospital. We believe that gaining acceptance with such centers of excellence could enhance our ability to gain acceptance at other regional and national medical centers. We also are focused on providing in-service training to hospitals to assure that SURFAXIN is administered in a safe and consistent manner.

  Our experience has suggested that the introduction of our hospital-based products, through the formulary acceptance process, pharmacy intake, delivery to NICUs, in-servicing and training, and actual use, is and will continue to be a lengthy process, and subject to a variety of potential delays and other factors not within our control. For that reason, we anticipate that revenues from sales of SURFAXIN will be modest in the next several years. In addition, to better inform the formulary committee review process and properly explain the method of administration and the potential benefits of SURFAXIN, including both potential medical and pharmacoeconomic benefits, we adjusted our approach to emphasize primarily medical education and scientific discussions in our formulary process. To accomplish this shift, as previously reported, in the second quarter of 2014, we resized and realigned our commercial and medical affairs teams.

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

  AEROSURF: We are conducting a phase 2a clinical trial for AEROSURF at four sites and currently are in the second half of our planned enrollments. This initial trial is 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 42 premature infants 29 to 34 weeks gestational age (GA) who are receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to infants receiving nCPAP alone. In addition, we hope to demonstrate that drug is being effectively delivered into the lungs. Overall, the rates of enrollment have been slower than expected. We also have implemented preparatory activities for the planned phase 2b clinical trial and, through this process, have identified four new clinical sites that will begin enrolling patients in the phase 2a clinical trial beginning in November 2014. We expect that these eight sites, based on their experience and knowledge of AEROSURF from the phase 2a program, will be positioned to be transitioned to the next phase of the clinical program. Based upon our most recent assessment of the clinical trial plan, we now anticipate completion of the phase 2a clinical trial in the first quarter of 2015, and completion of the phase 2b clinical trial in the first half of 2016.

In October 2014, we entered into a collaboration with Battelle Memorial Institute (Battelle) providing for the further development of our CAG for potential use in our planned phase 3 clinical program for AEROSURF for the treatment of RDS in premature infants and, if AEROSURF is approved, initial commercial supply. We and Battelle have agreed to work together to (i) define the requirements of the phase 3 CAG and disposable dose packs (together, AEROSURF System) and a detailed project plan for the project (Stage 1), (ii) develop the AEROSURF System in accordance with the project plan (Stage 2), and (iii) complete all required testing, verification and documentation to be in a position to manufacture AEROSURF Systems (Stage 3). Upon completion of the three-stage project plan, we and Battelle intend to negotiate in good faith to enter into an agreement for the manufacture of AEROSURF Systems for the AEROSURF phase 3 clinical program, and, if AEROSURF is approved, to negotiate in good faith to enter into a supply agreement providing for an initial commercial supply of AEROSURF Systems. We and Battelle will share equally in the costs of Stage 1 activities. Following completion of Stage 1, we and Battelle will agree on the details and projected costs for Stages 2 and 3. The parties will share equally in the costs of the project plan for Stages 2 and 3 as set forth in the project plan. Battelle will bear the entire cost of any cost overruns associated with execution of the project plan and the Company will bear the entire cost of any increase in the agreed upon project plan costs resulting from changes in the scope of the product requirements as agreed in Stage 1 and set forth in the project plan. Upon completion of the three-stage project plan, we and Battelle intend to negotiate in good faith to enter into an agreement for the manufacture of AEROSURF Systems for the AEROSURF phase 3 clinical program, and, if AEROSURF is approved, to negotiate in good faith to enter into a supply agreement providing for an initial commercial supply of AEROSURF Systems. *See,* Note 9, "– Subsequent Event," in the Notes to Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q.

If we are able to successfully complete our collaboration with Battelle as currently planned, we anticipate that our investment over the next two years will be approximately $5 million to $8 million for all device development activities to be in a position to manufacture AEROSURF Systems for use in the planned AEROSURF phase 3 clinical program and, if approved, initial commercialization.

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

For SURFAXIN, our approved KL4 surfactant in liquid form, we are actively engaged in discussions with the landlord of our manufacturing facility in Totowa, NJ (Totowa Facility) potentially to secure an extension of our lease, which currently is scheduled to expire on June 30, 2015. At the present time, our Totowa Facility is the only approved manufacturing facility for SURFAXIN commercial product. We understand that the landlord is pursuing strategic options for the entire facility. We are also pursuing potentially manufacturing SURFAXIN using third-party contract manufacturing organizations (CMOs). At this time, however, we are unable to complete a technology transfer of our SURFAXIN liquid KL4 surfactant manufacturing process in time to secure FDA approval for a new manufacturer of SURFAXIN prior to the scheduled expiration date of our lease. Accordingly, our primary goal is to secure longer-term utilization of our Totowa Facility. We cannot provide any assurance that we will be successful. If we do not succeed, we most likely will experience an interruption in supply of SURFAXIN drug product. *See,* Item 1A "–Risk Factors."

We are working 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. Patheon successfully manufactured a sufficient supply of lyophilized KL4 surfactant drug product to support our preclinical drug development activities, development activities for our phase 2 clinic-ready CAG, as well as our ongoing phase 2a clinical trial. We are working with Patheon to manufacture additional clinical supply to support our phase 2b clinical trial and have entered into a development agreement for the potential further development and manufacture of lyophilized KL4 surfactant for our potential AEROSURF phase 3 clinical program, as well as other potential pipeline development programs. In addition, we are advised that Patheon intends to close the building in which our development activities have occurred. As a result, we are implementing a technology transfer of our lyophilized KL4 surfactant manufacturing process to a new location in the Patheon campus in anticipation of manufacturing our lyophilized KL4 surfactant for use in our planned phase 3 clinical trial.

- In the second quarter of 2014, we secured three additional patents in the U.S., including two patents containing composition of matter and method of making claims for our lyophilized KL4 surfactant, which extend to March 2033, and one related to our novel AFECTAIR® aerosol-conducting airway connector for infants that extends to April 2029. In the third quarter of 2014, we have begun the process to prosecute these patents in various other countries. We believe that these patents are indicative of our efforts to protect the long-term commercial potential of our KL4 surfactant and aerosol delivery technologies. Our lyophilized KL4 surfactant is being developed initially for our AEROSURF development program. Our longer-term goal is to develop our technologies to address other potential indications that could benefit from our proprietary KL4 surfactant.

CRITICAL ACCOUNTING POLICIES

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

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. generally accepted accounting principles (GAAP) when it becomes effective. The new standard is effective for us in the annual period ending December 31, 2017, including interim periods within that annual period. Early application is not permitted. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements – Going Concern*, which requires management to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The standard defines substantial doubt as when it is probable (i.e., likely) that the entity will be unable to meet its obligations as they become due within one year of the date the financial statements are issued (or available to be issued, when applicable). The ASU is effective for the annual period ending December 31, 2016 and interim periods thereafter. Early application is permitted. We are evaluating the effect that ASU 2014-15 will have on our consolidated financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the three months ended September 30, 2014 and 2013 was $11.3 million (or $0.13 basic net loss per share) and $12.2 million (or $0.22 basic net loss per share), respectively. Included in the net loss is (i) the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.2 million and non-cash expense of $1.1 million for 2014 and 2013, respectively, and (ii) interest expense of $1.2 million and $0.4 million for 2014 and 2013, respectively, associated with the Deerfield Loan.

The net loss for the nine months ended September 30, 2014 and 2013 was $33.4 million (or $0.39 basic net loss per share) and $33.5 million (or $0.68 basic net loss per share), respectively. Included in the net loss is (i) the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $2.0 million and $1.6 million for 2014 and 2013, respectively, and (ii) interest expense of $3.4 million and $0.9 million for 2014 and 2013, respectively, associated with the Deerfield Loan.

The operating loss for the three months ended September 30, 2014 and 2013 was $10.3 million and $10.8 million, respectively. The decrease in operating loss from 2013 to 2014 was due to a $0.4 million increase in grant revenues.

The operating loss for the nine months ended September 30, 2014 and 2013 was $32.0 million and $34.2 million, respectively. The decrease in operating loss from 2013 to 2014 was due to a $1.2 million increase in grant revenues and a $0.9 million decrease in operating expenses.

Product Sales

In accordance with our revenue recognition policy, we recognize revenue once product has been sold through to the hospital and all revenue recognition criteria have been met. For the three and nine months ended September 30, 2014, we recognized revenue in the amount of $106,000 and $176,000, respectively. No product sales revenue was recognized for the three and nine months ended September 30, 2013.

Grant Revenue

We recognized grant revenue of $0.4 million and $1.5 million, respectively, for the three and nine months ended September 30, 2014. During the second quarter of 2014, we were awarded the final $1.9 million of a $2.4 million Fast Track Small Business Innovation Research (SBIR) Grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). This award provides support for the ongoing phase 2a clinical trial for AEROSURF. Our eligibility to be considered under this grant program was originally confirmed in 2010, and we previously received $0.6 million to support development activities related to our capillary aerosol generator technology. We expect to utilize the balance of the grant in the fourth quarter of 2014.

We recognized grant revenue of $0.1 million and $0.3 million for the three and nine months ended September 30, 2013, respectively. The grant funds were received and expended under a $0.6 million SBIR Phase I award from NIH's National Institute of Allergy and Infectious Diseases (NIAID) Center for Medical Counter Measures Against Radiation and Nuclear Threats to assess the ability of KL4 surfactant to mitigate the effects of acute radiation exposure to the lung, including acute pneumonitis and delayed lung injury.

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. Over the next three years, we may be awarded up to an additional $2.0 million as part of this grant. We did not recognize any revenue from this grant during the quarter ended September 30, 2014. We expect to utilize the $1.0 million grant beginning in the fourth quarter of 2014 through the first half of 2015.

Cost of product sales

Cost of product sales for the three and nine months ended September 30, 2014 was $0.3 million and $1.8 million, respectively, and primarily represents reserves for SURFAXIN finished goods inventories that are not anticipated to be recoverable through the commercial sale of the product during the initial launch period due to product expiration.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and are tracked by category rather than by development project. As many of our research and development activities form a foundation for the development of our KL4 surfactant and drug delivery technologies, they are expected to benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist of expenses associated with (a) product development and manufacturing, (b) medical and regulatory operations, (c) direct preclinical and clinical programs, and (d) other related expenses.

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

(in thousands)	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Product development and manufacturing	$ 3,806	$ 4,769	$ 10,728	$ 16,591
Medical and regulatory operations	2,001	1,506	5,848	4,416
Direct preclinical and clinical programs	664	299	2,343	902
Total Research & Development Expenses	$ 6,471	$ 6,574	$ 18,919	$ 21,909

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.5 million and $0.4 million for the three months ended September 30, 2014 and 2013, respectively; and $1.4 million and $1.1 million for the nine months ended September 30, 2014 and 2013, respectively.

Product Development and Manufacturing

Product development and manufacturing includes (i) manufacturing operations, both in-house and with CMOs, validation activities and quality assurance and analytical chemistry capabilities to support production of drug supply for our KL4 surfactant products used in research and development activities, and of medical devices, including CAG and AFECTAIR devices, (ii) design and development activities related to our CAG device for use in our AEROSURF clinical program; and (iii) pharmaceutical and manufacturing development activities, including development of a lyophilized dosage form of our KL4 surfactant. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality control and assurance activities, analytical services, and expert consultants and outside services to support pharmaceutical and device development activities.

Product development and manufacturing expenses for the three months ended September 30, 2014 decreased $1.0 million compared to the same period in 2013, due to (i) investments of $0.7 million in 2013 to complete development activities for our phase 2 clinic-ready CAG device, including work that began in June 2012 with Battelle, which assisted with the device design and testing, and manufactured a supply of clinic-ready CAG devices for use in the initial AEROSURF phase 2a clinical trial, and (ii) $0.3 million in the third quarter of 2013 to support the development of our lyophilized KL4 surfactant manufacturing process at Patheon.

Product development and manufacturing expenses for the nine months ended September 30, 2014 decreased $5.9 million compared to the same period in 2013, due to (i) investments in 2013 of $3.3 million to complete development activities for our phase 2 clinic-ready CAG device for use in our AEROSURF phase 2 clinical trials, (ii) $2.1 million of costs capitalized to SURFAXIN inventory in 2014, and (iii) a reduction of $1.2 million in purchases of APIs used in the manufacture of SURFAXIN commercial drug product and our lyophilized KL4 surfactant for use in preclinical and clinical development activities, including the technology transfer of our KL4 surfactant manufacturing process to Patheon, and activities to prepare for our AEROSURF phase 2 clinical program.

Medical and Regulatory Operations

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

Medical and regulatory operations expenses for the three months ended September 30, 2014 increased $0.5 million compared to the same period in 2013 due to a $0.4 million increase in employee-related costs as we strengthen our clinical leadership team and regulatory capabilities to support our AEROSURF development program.

Medical and regulatory operations expenses for the nine months ended September 30, 2014 increased $1.4 million compared to the same period in 2013 due to (i) a $0.8 million increase in employee-related costs as we strengthen our clinical leadership team and regulatory capabilities to support our AEROSURF development program, and (ii) a $0.3 million increase related to our medical affairs capabilities to execute the commercial introduction of SURFAXIN.

Direct Preclinical and Clinical Programs

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

Direct preclinical and clinical programs expenses for the three months ended September 30, 2014 increased $0.4 million compared to the same period in 2013 due to a $0.3 million increase in AEROSURF clinical trial activities, including ongoing enrollment of the Phase 2a study and initiating the manufacture of clinic-ready CAG devices for the planned AEROSURF Phase 2b clinical study.

Direct preclinical and clinical programs expenses for the nine months ended September 30, 2014 increased $1.4 million compared to the same period in 2013 due to (i) a $1.1 million increase in AEROSURF clinical trial activities, including ongoing enrollment of the Phase 2a study and initial manufacturing of clinic-ready CAG devices for the planned AEROSURF Phase 2b clinical study, and (ii) $0.5 million of preclinical activities in 2014 related to our lyophilized dosage form of our KL_4 surfactant.

We anticipate that our expected direct clinical program costs will increase over the next few years as we refine our plans following review of the results and learnings of our phase 2a program and execute the later stages of the planned AEROSURF clinical development 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 "Item 1 – Business – Government Regulation," "Item 1A – Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Research and Development Expenses" in our 2013 Form 10-K.

Our research and development projects have been focused initially on the management of RDS in premature infants, and include (i) SURFAXIN liquid instillate, which was approved by the FDA in 2012 and introduced commercially in 2013, (ii) our lyophilized KL_4 surfactant, which we are developing initially for use in our AEROSURF development program and, if we are able to gain FDA agreement for a development program that would be both capital efficient and capable of implementation within a reasonable time, potentially, SURFAXIN LS; (iii) our aerosol delivery technology, in particular the development of a CAG device to support our AEROSURF phase 2 clinical program; and (iv) AEROSURF phase 2 clinical trial activities and preparatory work for the planned AEROSURF phase 3 clinical program. These and our other development programs are described "Item 1 – Business – Proprietary Platform – Surfactant and Aerosol Technologies," and "- Surfactant Replacement Therapy for Respiratory Medicine" in our 2013 Form 10-K, and in our other periodic filings with the SEC.

To prepare for initiation of 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 KL_4 surfactant, further development of a CAG device under our collaboration with Battelle, and the conduct of the planned clinical trials. In particular, we anticipate that direct clinical program costs for AEROSURF will increase significantly over the next few years as we refine our plans following review of the results and learnings of our phase 2a program and execute the later stages of the planned AEROSURF clinical development program.

At the present time, we are focusing our efforts primarily on the commercial introduction of SURFAXIN and the development of AEROSURF through the phase 2 clinical trials to the planned phase 3 clinical program. We believe, however, that in the future we may be able to leverage the information, data and know-how that we gain from our work with SURFAXIN and AEROSURF to support development of a robust product pipeline that could address serious critical care respiratory conditions in larger children and adults in PICUs and ICUs, including potentially ALI, COPD and CF.

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

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Selling, General and Administrative Expenses	$ 4,126	$ 4,299	$ 12,995	$ 12,648

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.

Change in Fair Value of Common Stock Warrant Liability

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Change in fair value of common stock warrant liability	$ 173	$ (1,059)	$ 1,999	$ 1,627

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 6, "– 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" our 2013 Form 10-K.

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

Other Income and (Expense)

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Interest income	$ 2	$ 1	$ 6	$ 2
Interest expense	(1,172)	(353)	(3,396)	(873)
Other income / (expense), net	$ (1,170)	$ (352)	$ (3,390)	$ (871)

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

Interest expense consists of interest expense associated with the Deerfield Loan (*see,* Note 7, "– Deerfield Loan," in the Notes to Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q) and interest expense incurred under our equipment financing facilities. Amounts outstanding under the Deerfield Loan as of September 30, 2014 and 2013 were $30.0 million and $10.0 million, respectively.

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Cash interest expense	$ 662	$ 221	$ 1,963	$ 551
Non-cash amortization of debt discounts	504	125	1,414	302
Amortization of debt costs	5	5	15	13
Total interest expense	$ 1,171	$ 351	$ 3,392	$ 866

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

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, and, more recently, commercialization and medical affairs activities, and we expect to continue to incur substantial losses over the next several years. Historically, we have funded our business operations through various sources, including public and private securities offerings, debt facilities, strategic alliances, the use of committed equity financing facilities (CEFFs) and at-the-market (ATM) equity programs, and capital equipment financings.

As of September 30, 2014, we had cash and cash equivalents of $54.9 million and long-term debt of $30 million ($19.8 million net of discount) under our loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see,* Note 7, "– Deerfield Loan," in the Notes to Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q). Before any additional financings, including under our ATM Program (*see*, Note 11 - "At-the-Market Program (ATM Program)," to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2013 (2013 Form 10-K)), we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the third quarter of 2015.

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

Our future capital requirements will depend upon many factors, primarily our efforts to (i) execute the commercial introduction of SURFAXIN in the U.S.; (ii) assure long-term continuity of supply for our commercial liquid, lyophilized and aerosolized KL4 surfactant drug product, at our manufacturing facility in Totowa, NJ (Totowa Facility) and with CMOs, (iii) advance the AEROSURF development program to completion of the phase 2 clinical trials as planned; (iv) further the development of our CAG for use in a planned phase 3 clinical program and, if approved, early commercial activities, (v) prepare for and conduct an AEROSURF phase 3 clinical program; and (vi) secure one or more strategic alliances or other collaboration arrangements to support our development programs and commercialization of our approved products, if any, in markets outside the U.S. We believe that we will be better positioned to enter into a significant strategic alliance if we are successful in advancing the commercial introduction of SURFAXIN, and completing and obtaining encouraging results from the AEROSURF phase 2 clinical program within our anticipated time.

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

As of September 30, 2014, we had outstanding warrants to purchase approximately 14 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, warrants to purchase 7 million shares were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share (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 contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. These warrants currently have an exercise price of $1.50 per share and expire in February 2016. In addition, in October 2014, we issued to Battelle Memorial Institute (Battelle) warrants to purchase 1.5 million shares of our common stock at an exercise price of $5.00, with a 10-year term, exercisable upon achievement of a development milestone defined in the related Collaboration Agreement with Battelle of the same date, provided that the purchase of .5 million shares is subject to the further condition that the milestone be achieved on or before May 31, 2016. *See,* Note 9, "– Subsequent Event," in the Notes to Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q. Although we could receive additional capital from the exercise of any of our outstanding warrants for cash, there can be no assurance that the market price of our common stock will equal or exceed price levels that would make exercise of outstanding warrants likely, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

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

Cash Flows

As of September 30, 2014, we had cash and cash equivalents of $54.9 million compared to $86.3 million as of December 31, 2013. Cash outflows before financing activities for the nine months ended September 30, 2014 consisted of $31.1 million used for ongoing operating activities and $0.7 million for purchases of property and equipment. Cash provided by financing activities were $0.4 million of proceeds from the exercise of warrants and stock options.

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2014 and 2013 was $31.1 million and $30.4 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2014 and 2013 represents capital expenditures of $0.7 million and $0.2 million, respectively. The increase in capital expenditures is due to timing of routine equipment purchases.

Financing Activities

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

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

Common Stock Offerings

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of common stock offerings. In May 2014, we filed with the SEC a universal shelf registration statement on Form S-3 (No. 333-196420) (2014 Universal Shelf) that was declared effective on June 13, 2014 for the proposed offering from time to time of up to $250 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at the time of an offering. The 2014 Universal Shelf replaces an expired 2011 Universal Shelf. As of September 30, 2014, after reserves for outstanding unexercised warrants and amounts remaining under our ATM Program, approximately $199.0 million remained available under the 2014 Universal Shelf. The 2014 Universal Shelf will expire in June 2017.

At-the-Market Program (ATM Program)

We have an ATM Program with Stifel, Nicolaus & Company, Incorporated (Stifel), under which Stifel, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell up to a maximum of $25 million of our common stock over a three-year period ending February 11, 2016. We are not required to sell any shares at any time during the term of the ATM Program. We have agreed to pay Stifel a commission of 3% of gross proceeds of any sales of shares. *See,* "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – At-the-Market Program (ATM Program) – Stifel ATM Program," in our 2013 Form 10-K. As of September 30, 2014, approximately $23 million shares of common stock remained available under the ATM Program.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Our management, including our President and Chief Executive Officer (principal executive officer) and our 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 controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not aware of any pending or threatened legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the conduct of our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

ITEM 1A. RISK FACTORS

Investing in our securities involves risks. In addition to the other information in this quarterly report on Form 10-Q, stockholders and potential investors should carefully consider the risks and uncertainties discussed in the section "Item 1A – Risk Factors" in our 2013 Form 10-K, as supplemented by the risks and uncertainties discussed below and elsewhere in this Quarterly Report on 10-Q. The risks and uncertainties discussed in this Quarterly Report on Form 10-Q and described in our 2013 Form 10-K are not the only ones that may materialize. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations. If any of the risks and uncertainties discussed in this Quarterly Report on Form 10-Q or in our 2013 Form 10-K actually materialize, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment.

The projections that we may make from time to time are subject to inherent risks.

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

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

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

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

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

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

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

We currently manufacture SURFAXIN at our manufacturing operations in Totowa, New Jersey (Totowa Facility), for which our lease is currently scheduled to expire in June 2015. Under our Collaboration Agreement with Battelle, we will negotiate in good faith for the manufacture of AEROSURF Systems for planned phase 2 clinical program and, if approved, initial commercialization. We also manufacture our lyophilized KL4 surfactant, CAG, WARMING CRADLE® and AFECTAIR® devices with CMOs. Our manufacturing plans could expose us to the following risks:

— We are currently in discussions with our landlord to potentially secure long-term utilization of that facility. We cannot provide any assurance that we will succeed, and if we are unsuccessful, we most likely will experience an interruption in supply of SURFAXIN drug product.

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

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

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

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

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

— Should we desire to make our drug products and/or devices available outside the U.S. for commercial or clinical purposes, our CMOs would become subject to, and may be unable to comply with, corresponding cGMPs and QSRs of foreign regulators having jurisdiction over our activities abroad. Such failures could restrict our ability to execute our business strategies.

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

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

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

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

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

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

In addition, if in our clinical trials we succeed in achieving our patient enrollment targets, our patients could suffer adverse medical events or side effects that are known to be associated with surfactant administration, such as a decrease in the oxygen level of the blood, or currently unknown to us. It is also possible that our AEROSURF Clinical Trial (ACT) Steering Committee, the Safety Review Committee (SRC), the FDA, or we could interrupt, delay or halt any one or more of our clinical trials for AEROSURF or any of our product candidates. For example, in our phase 2a AEROSURF clinical trial, we have observed known complications of prematurity expected in this patient population. We have seen numerically more pneumothoraces in the AEROSURF-treated group at a rate within the range reported for this population in medical literature. Otherwise, the adverse event profile of the AEROSURF-treated group is generally comparable to the control group. These data have been reviewed with our medical advisors, expert consultants and SRC members, and they will continue to do so as the trial proceeds. If our ACT Steering Committee, the SRC, any regulator or we believe that study participants face unacceptable health risks, any one or more of our clinical trials could be suspended or terminated. In addition, clinical trials may be interrupted, delayed or halted, in whole or in part, for reasons other than health and safety concerns, including, among other things, matters related to the design of the study, drug availability, ACT Steering Committee and/or SRC recommendation, or business reasons. Even if we timely complete a clinical trial, we may fail to achieve the desired endpoints.

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

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

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2014, we had cash and cash equivalents of approximately $56 million and $30 million of long-term debt under our Deerfield Loan. Before any additional financings, including under our ATM Program, we anticipate that we will have sufficient cash available to support our current operations and debt service obligations through the third quarter of 2015.

We expect to continue to require significant additional infusions of capital to be able to execute key components of our long-term business strategy. For example, we expect to make potentially significant additional investments to (i) secure our long-term manufacturing capabilities for our liquid and lyophilized KL4 surfactant drug product, (ii) further the development of our CAG for use in a potential phase 3 clinical program and potential commercial applications, and (iii) prepare for, initiate and conduct a potential AEROSURF phase 3 clinical program.

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

ITEM 6. EXHIBITS

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

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: November 7, 2014

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

Date: November 7, 2014

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

INDEX TO EXHIBITS

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

Exhibit No.	Description	Method of Filing
3.1	Amended and Restated Certificate of Incorporation, as amended by a Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery) filed on June 10, 2014.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, as filed with the SEC on August 7. 2014.
3.2	Amended and Restated By-Laws of Discovery, as amended effective September 3, 2009.	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on September 4, 2009.
4.1	Form of Warrant to Purchase Common Stock issued in February 2010.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 18, 2010.
4.2	Warrant Agreement, dated as of April 30, 2010, by and between Discovery and PharmaBio.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
4.3	Warrant Agreement dated June 11, 2010 by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2010.
4.4	Form of Series I Warrant to Purchase Common Stock issued on June 22, 2010 (Five-Year Warrant).	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 17, 2010.
4.5	Warrant Agreement, dated as of October 12, 2010, by and between Discovery and PharmaBio.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on October 13, 2010.
4.6	Form of Series I Warrant to Purchase Common Stock issued on February 22, 2011 (Five-Year Warrant).	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 16, 2011.
4.9+	Form of Warrant dated February 13, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) under a Facility Agreement dated as of February 13, 2012 (Facility Agreement) between Discovery and Deerfield.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2013.
4.10+	Form of Warrant dated December 3, 2013, issued to Deerfield on December 3, 2013 under the Facility Agreement.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 6, 2013.

Exhibit No.	Description	Method of Filing
4.11	Warrant, dated as of October 10, 2014, issued to Battelle Memorial Institute (Battelle) under a Collaboration Agreement dated as of October 10, 2014 (Collaboration Agreement), between Battelle and Discovery	Filed herewith.
4.12	Second Warrant, dated as of October 10, 2014, issued to Battelle under the Collaboration Agreement	Filed herewith.
10.1*	Collaboration Agreement dated as of October 10, 2014, by and between Battelle and Discovery.	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 September 30, 2014, formatted in Extensive Business Reporting Language (“XBRL”): (i) Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2014 and September 30, 2013, (iii) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2014 and September 30, 2013, and (v) Notes to consolidated financial statements.	

Exhibit No.	Description	Method of Filing
101.INS	Instance Document.	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.

+ Confidential treatment requested and granted by the Commission as to certain portions of these exhibits. Such portions have been redacted and filed separately with the Commission.

* Confidential treatment requested as to certain portions of these exhibits. Such portions have been redacted and filed separately with the Commission.

Exhibit 4.11

THIS WARRANT AND ANY SECURITIES ACQUIRED UPON THE EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE, AND MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND APPLICABLE STATE SECURITIES LAWS OR PURSUANT TO AN APPLICABLE EXEMPTION TO THE REGISTRATION REQUIREMENTS OF SUCH ACT AND SUCH LAWS. THIS WARRANT AND SUCH SECURITIES MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF EXCEPT IN COMPLIANCE WITH THE CONDITIONS SPECIFIED HEREIN.

DISCOVERY LABORATORIES, INC.
FORM OF WARRANT TO PURCHASE COMMON STOCK

Warrant No.: BMI00001
Number of Shares of Common Stock: 1,000,000
Date of Issuance: October 10, 2014 ("**Issuance Date**")

Discovery Laboratories, Inc., a Delaware corporation (the "**Company**"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, **Battelle Memorial Institute** ("**Battelle**"), the registered holder hereof or its permitted assigns (the "**Holder**"), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "**Warrant**"), at any time or times on or after the Exercise Date (defined below), but not after 11:59 p.m., New York time, on the Expiration Date (defined below), One Million (1,000,000) fully paid nonassessable shares of Common Stock (as defined below) (the "**Warrant Shares**"). This Warrant is issued in conjunction with that certain Collaboration Agreement (the "**Collaboration Agreement**") by and between the Company and Battelle, dated October 10, 2014, entered into in conjunction herewith. Except as otherwise defined herein, capitalized terms in this Warrant shall have the meanings set forth in Section 16.

1. EXERCISE OF WARRANT.

(a) Mechanics of Exercise. Subject to the terms and conditions hereof, this Warrant may be exercised by the Holder on any day on or after the date on which Battelle shall have achieved the Device Development Milestone (as that term is defined in the Collaboration Agreement) (the "**Exercise Date**"), in whole or in part, upon (i) surrender of this Warrant, with a notice in the form attached hereto as Exhibit A (the "**Exercise Notice**"), duly completed and executed by an authorized officer of the Holder, together with such evidence of authority as the Company may reasonably request, and (ii) (A) payment of the Exercise Price multiplied by the number of Warrant Shares as to which this Warrant is being exercised (the "**Aggregate Exercise Price**") in cash or by wire transfer of immediately available funds or (B) provided the conditions for cashless exercise set forth in Section 1(d) are satisfied, by notifying the Company that this Warrant is being exercised pursuant to a Cashless Exercise (as defined in Section 1(d)); at the office of the Company, 2600 Kelly Road, Suite 100, Warrington, PA 18976, Phone: (215) 488-9300, Fax: (215) 488-9421, electronic mail (Warrants@discoverylabs.com). On or before the third (3rd) Business Day (the "**Share Delivery Date**") following the date on which the Company has received each of the Exercise Notice and the Aggregate Exercise Price (or notice of a Cashless Exercise) (collectively, the "**Exercise Documents**"), the Company shall (X) provided that Continental Stock Transfer & Trust Company (the Company's "**Transfer Agent**") is participating in The Depository Trust Company ("**DTC**") Fast Automated Securities Transfer Program, upon the request of the Holder, credit such aggregate number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit/Withdrawal At Custodian ("**DWAC**") system, or (Y) if the Transfer Agent is not participating in the DTC Fast Automated Securities Transfer Program or the Holder does not request delivery of the Warrant Shares via DWAC, issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise. Upon delivery of the Exercise Documents, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or delivered in certificate form, as the case may be. If this Warrant is submitted to exercise a number of Warrant Shares in connection with any exercise and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the number of Warrant Shares being acquired upon an exercise, then the Company shall as soon as practicable and in no event later than three Business Days after any exercise and at its own expense, issue a new Warrant (in accordance with Section 8(d)) representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, reduced by the number of Warrant Shares being exercised. No fractional shares of Common Stock are to be issued upon the exercise of this Warrant, but rather the number of shares of Common Stock to be issued shall be rounded down to the nearest whole number. The Company shall pay any and all taxes which may be payable with respect to the issuance and delivery of Warrant Shares upon a partial exercise of this Warrant.

(b) Exercise Price. For purposes of this Warrant, "**Exercise Price**" means $5.00, subject to adjustment as provided herein.

(c) Company's Failure to Timely Deliver Securities. If the Company shall fail for any reason or for no reason to issue to the Holder within three (3) Business Days of receipt of the Exercise Documents in compliance with the terms of this Section 1, a certificate for the number of shares of Common Stock to which the Holder is entitled and register such shares of Common Stock on the Company's share register or to credit the Holder's balance account with DTC for such number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise of this Warrant, and if on or after such Trading Day the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of shares of Common Stock issuable upon such exercise that the Holder anticipated receiving from the Company (a **"Buy-In"**), then the Company shall, within three (3) Business Days after the Holder's request, (1) pay cash to the Holder in the amount by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased in the Buy-in, exceeds (y) the amount obtained by multiplying (A) the number of Warrant Shares that the Company has failed to deliver in connection with the exercise, by (B) the price at which the sell order giving rise to the Buy-in was executed; and (2) at the option of the Holder, either (xx) provided that a registration statement covering the issuance of the Warrant Shares that are the subject of the Exercise Notice is effective, deliver to the Holder the number of Warrant Shares that would have been issued had the Company timely complied with the Exercise Notice and its delivery obligations hereunder, or (yy) provided the conditions for cashless exercise set forth in Section 1(d) are satisfied, notify the Company that the Warrant should be exercised pursuant to a Cashless Exercise (as defined in Section 1(d)), or (zz) reinstate that portion of the Warrant and equivalent number of Warrant Shares that the Company failed to deliver (prior to receipt by the Holder of the Exercise Shares),

(d) Cashless Exercise. Notwithstanding anything contained herein to the contrary, if, but only if, a registration statement covering the issuance of the Warrant Shares that are the subject of the Exercise Notice (the "**Unavailable Warrant Shares**") is not effective and an exemption from registration for the issuance and resale of such Unavailable Warrant Shares would only be available if the exercise of the Warrant were effected pursuant to a Cashless Exercise in accordance with this Section 1(d), then the Holder may exercise this Warrant in whole or in part and, in lieu of making the cash payment upon such exercise in payment of the Aggregate Exercise Price, elect instead to receive upon such exercise the "Net Number" of shares of Common Stock determined according to the following formula (a "**Cashless Exercise**"):

$$\text{Net Number} = \frac{(A \times B) - (A \times C)}{B}$$

For purposes of the foregoing formula:

A= the total number of shares with respect to which this Warrant is then being exercised.

B= the arithmetic average of the Closing Sale Prices of the shares of Common Stock for the five (5) consecutive Trading Days ending on the Trading Day immediately preceding the date of the Exercise Notice.

C= the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For sake of clarity, in the event that neither a registration statement nor an exemption from registration is available, there is no circumstance that would require the Company to effect a net cash settlement of the Warrants.

(e) Rule 144. For purposes of Rule 144(d) promulgated under the Securities Act of 1934 (the "**Securities Act**"), as in effect on the date hereof, it is intended that the Warrant Shares issued in a Cashless Exercise shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued pursuant to the Underwriting Agreement.

(f) Disputes. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed, and all such disputes shall be resolved pursuant to Section 13.

(g) Beneficial Ownership. The Company shall not effect the exercise of this Warrant, and the Holder shall not have the right to exercise this Warrant, to the extent that after giving effect to such exercise, such Person (for the purpose of this clause (g), together with such Person's affiliates) would beneficially own in excess of 9.99% (the "**Maximum Percentage**") of the shares of Common Stock outstanding immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by such Person and its affiliates shall include the number of shares of Common Stock of this Warrant being exercised, but shall exclude shares of Common Stock issuable upon (i) exercise of any unexercised portion of this Warrant beneficially owned by such Person and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by such Person (including, without limitation, any convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein. Except as set forth in the preceding sentence, for purposes of this paragraph, beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended. For purposes of this Warrant, in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (1) the Company's most recent public filing with the Securities and Exchange Commission, (2) a more recent public announcement by the Company or (3) any notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. To the extent that the limitation contained in this Section 1(g) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of an Exercise Notice shall be deemed to be each Holder's determination of whether this Warrant is exercisable and which portion of this Warrant is exercisable, and the Company shall have no obligation to verify or confirm the accuracy of such determination. For any reason at any time, upon the written or oral request of the Holder, the Company shall within two (2) Business Days confirm to the Holder the number of shares of Common Stock then outstanding. This Section 1(g) shall be construed and implemented in a manner otherwise than in strict conformity with its terms to correct this paragraph or any portion of this paragraph which may be defective or inconsistent with the intended beneficial ownership limitation or to make changes or supplements necessary or desirable to properly give effect to such limitation.

2. ADJUSTMENT OF EXERCISE PRICE AND NUMBER OF WARRANT SHARES. The Exercise Price and the number of Warrant Shares shall be adjusted from time to time as follows:

(a) Adjustment upon Subdivision or Combination of Common Stock. If the Company at any time on or after the Issuance Date subdivides (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise) one or more classes of its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced and the number of Warrant Shares will be proportionately increased. If the Company at any time on or after the Pricing Date combines (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise) one or more classes of its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination will be proportionately increased and the number of Warrant Shares will be proportionately decreased. Any adjustment under this Section 2(a) shall become effective at the close of business on the date the subdivision or combination becomes effective.

(b) Other Events. If any event occurs of the type contemplated by the provisions of this Section 2 but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features), then the Company's Board of Directors will make an appropriate adjustment in the Exercise Price and the number of Warrant Shares so as to protect the rights of the Holder; provided that no such adjustment pursuant to this Section 2(b) will increase the Exercise Price or decrease the number of Warrant Shares as otherwise determined pursuant to this Section 2.

3. RIGHTS UPON DISTRIBUTION OF ASSETS. If the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to all holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "**Distribution**"), at any time after the issuance of this Warrant, then, in each such case:

(a) any Exercise Price in effect immediately prior to the close of business on the record date fixed for the determination of holders of shares of Common Stock entitled to receive the Distribution shall be reduced, effective as of the close of business on such record date, to a price determined by multiplying such Exercise Price by a fraction of which (i) the numerator shall be the Closing Bid Price of the shares of Common Stock on the Trading Day immediately preceding such record date minus the value of the Distribution (as determined in good faith by the Company's Board of Directors) applicable to one share of Common Stock, and (ii) the denominator shall be the Closing Bid Price of the shares of Common Stock on the Trading Day immediately preceding such record date; and

(b) the number of Warrant Shares shall be increased to a number of shares equal to the number of shares of Common Stock obtainable immediately prior to the close of business on the record date fixed for the determination of holders of shares of Common Stock entitled to receive the Distribution multiplied by the reciprocal of the fraction set forth in the immediately preceding paragraph (a); *provided* that in the event that the Distribution is of shares of Common Stock (or common stock) ("**Other Shares of Common Stock**") of a company whose shares of common stock are traded on a national securities exchange or a national automated quotation system, then the Holder may elect to receive a warrant to purchase Other Shares of Common Stock in lieu of an increase in the number of Warrant Shares, the terms of which shall be identical to those of this Warrant, except that such warrant shall be exercisable into the number of shares of Other Shares of Common Stock that would have been payable to the Holder pursuant to the Distribution had the Holder exercised this Warrant immediately prior to such record date and with an aggregate exercise price equal to the product of the amount by which the exercise price of this Warrant was decreased with respect to the Distribution pursuant to the terms of the immediately preceding paragraph (a) and the number of Warrant Shares calculated in accordance with the first part of this paragraph (b).

4. PURCHASE RIGHTS; FUNDAMENTAL TRANSACTIONS.

(a) Purchase Rights. In addition to any adjustments pursuant to Section 2 above, if at any time the Company grants, issues or sells any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "**Purchase Rights**"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights.

(b) Fundamental Transactions. The Company shall not enter into or be party to a Fundamental Transaction unless the Successor Entity assumes this Warrant in accordance with the provisions of this Section (4)(b), including agreements to deliver to each holder of Warrants in exchange for such Warrants a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant, including, without limitation, an adjusted exercise price equal to the value for the shares of Common Stock reflected by the terms of such Fundamental Transaction, and exercisable for a corresponding number of shares of capital stock equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and satisfactory to the Holder. Upon the occurrence of any Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein. Upon consummation of the Fundamental Transaction, the Successor Entity shall deliver to the Holder confirmation that there shall be issued upon exercise of this Warrant at any time after the consummation of the Fundamental Transaction, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property) purchasable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had this Warrant been converted immediately prior to such Fundamental Transaction, as adjusted in accordance with the provisions of this Warrant. In addition to and not in substitution for any other rights hereunder, prior to the consummation of any Fundamental Transaction pursuant to which holders of shares of Common Stock are entitled to receive securities or other assets with respect to or in exchange for shares of Common Stock (a "**Corporate Event**"), the Company shall make appropriate provision to insure that the Holder will thereafter have the right to receive upon an exercise of this Warrant at any time after the consummation of the Fundamental Transaction but prior to the Expiration Date, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property) purchasable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had the Warrant been exercised immediately prior to such Fundamental Transaction. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The provisions of this Section 4 shall apply similarly and equally to successive Fundamental Transactions and Corporate Events and shall be applied without regard to any limitations on the exercise of this Warrant.

5. NONCIRCUMVENTION. The Company hereby covenants and agrees that the Company will not, by amendment of its Certificate of Incorporation, Bylaws or through any reorganization, transfer of assets, consolidation, merger, scheme of arrangement, dissolution, issue or sale of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, and will at all times in good faith carry out all the provisions of this Warrant and take all action as may be required to protect the rights of the Holder. Without limiting the generality of the foregoing, the Company (i) shall not increase the par value of any shares of Common Stock receivable upon the exercise of this Warrant above the Exercise Price then in effect, (ii) shall take all such actions as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable shares of Common Stock upon the exercise of this Warrant, and (iii) shall, so long as this Warrant is outstanding, take all action necessary to reserve and keep available out of its authorized and unissued shares of Common Stock, solely for the purpose of effecting the exercise of this Warrant, 100% of the number of shares of Common Stock issuable upon exercise of this Warrant then outstanding (without regard to any limitations on exercise).

6. PRIVATE PLACEMENT; REGISTRATION RIGHTS

(a) Private Placement Representations. The Holder represents that it is an "accredited investor" within the meaning of Regulation D under the Securities Act who is acquiring the Warrants without having been offered or sold the Warrant by any form of "general solicitation" or "general advertising", in each case within the meaning of Regulation D under the Securities Act, and that the Warrants are being or will be acquired for its own account or for one or more separate accounts maintained by it or for the account of one or more pension or trust funds and not with a view toward distributing or reselling such securities or any part thereof in any transaction that would be in violation of the Securities Act, federal securities laws or the securities laws of any state, without prejudice, however, to its rights to sell or otherwise dispose of all or any part of the Warrants under an effective registration statement under the Securities Act and applicable state securities laws, or under an exemption from such registration available under the Securities Act and applicable state securities laws.

(b) Private Offering by the Company. Neither the Company nor anyone acting on its behalf has offered the Warrants for sale to, or solicited any offer to buy any of the same from, or otherwise approached or negotiated in respect thereof with, any person other than the Holders, each of which has been offered the Warrants at a private sale for investment. Neither the Company nor anyone acting on its behalf has taken, or will take, any action that would subject the issuance or sale of the Warrants to the registration requirements of section 5 of the Securities Act or to the registration requirements of any securities or blue sky laws of any applicable jurisdiction.

(c) Restrictive Legends. Each certificate for Warrant Shares issued upon the exercise of the Warrant, and each certificate issued upon the transfer of any such Warrant Shares, shall be stamped or otherwise imprinted with a legend in substantially the following form:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE, AND MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND APPLICABLE STATE SECURITIES LAWS OR PURSUANT TO AN APPLICABLE EXEMPTION TO THE REGISTRATION REQUIREMENTS OF SUCH ACT AND SUCH LAWS."

(d) Registration Rights. The Company and Holder shall negotiate in good faith and, prior to the Exercise Date, enter into a customary registration rights agreement providing for registration rights and procedures relating thereto that are mutually agreeable by the parties acting in good faith with respect to the Warrant Shares that Holder has the right to acquire pursuant the exercise of this Warrant.

7. WARRANT HOLDER NOT DEEMED A STOCKHOLDER. Except as otherwise specifically provided herein, the Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

8. REISSUANCE OF WARRANTS.

(a) Transfer of Warrant. If this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company together with a written assignment of this Warrant in the form attached hereto as Exhibit B duly executed by an authorized officer of the Holder or its agent or attorney, together with such evidence of authority as the Company may reasonably request, whereupon the Company will forthwith, subject to compliance with any applicable securities laws, issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 8(d)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 8(d)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred.

(b) Lost, Stolen or Mutilated Warrant. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary form and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company shall execute and deliver to the Holder a new Warrant (in accordance with Section 8(d)) representing the right to purchase the Warrant Shares then underlying this Warrant.

(c) Exchangeable for Multiple Warrants. This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company, for a new Warrant or Warrants (in accordance with Section 8(d)) representing in the aggregate the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; provided, however, that no Warrants for fractional shares of Common Stock shall be given.

(d) Issuance of New Warrants. Whenever the Company is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant (i) shall be of like tenor with this Warrant, (ii) shall represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Section 8(a) or Section 8(c), the Warrant Shares designated by the Holder which, when added to the number of shares of Common Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) shall have an issuance date, as indicated on the face of such new Warrant, which is the same as the Issuance Date, and (iv) shall have the same rights and conditions as this Warrant.

9. NOTICES. The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Warrant, including in reasonable detail a description of such action and the reason therefor. Whenever notice is required to be given under this Warrant, unless otherwise provided herein, such notice shall be given in writing, will be mailed (a) if within the domestic United States by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, or by facsimile or (b) if delivered from outside the United States, by International Federal Express or facsimile, and (c) will be deemed given (i) if delivered by first-class registered or certified mail domestic, three business days after so mailed, (ii) if delivered by nationally recognized overnight carrier, one business day after so mailed, (iii) if delivered by International Federal Express, two business days after so mailed and (iv) if delivered by facsimile, upon electronic confirmation of receipt, and will be delivered and addressed as follows:

(a) if to the Company, to:

Discovery Laboratories, Inc.
2600 Kelly Road
Warrington, Pennsylvania 18976
Attention: Chief Financial Officer
Facsimile: 215-488-9301

with copies to:

Discovery Laboratories, Inc.
2600 Kelly Road
Warrington, Pennsylvania 18976
Attention: General Counsel
Facsimile: 215-488-9557

(b) if to the Holder, at its address on the Exercise Notice in the form attached as Exhibit A hereto, or at such other address or addresses as may have been furnished to the Company in writing to the foregoing addresses.

10. AMENDMENT AND WAIVER. Except as otherwise provided herein, the provisions of this Warrant may be amended only with the written consent of the Company and the Holder, and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only with the written consent of the Holder.

11. GOVERNING LAW. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of Delaware, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Delaware or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Delaware.

12. CONSTRUCTION; HEADINGS. This Warrant shall be deemed to be jointly drafted by the Company and the Holder and shall not be construed against any person as the drafter hereof. The headings of this Warrant are for convenience of reference and shall not form part of, or affect the interpretation of, this Warrant.

13. DISPUTE RESOLUTION. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall submit the disputed determinations or arithmetic calculations via facsimile or electronic mail within two (2) Business Days of receipt of the Exercise Notice giving rise to such dispute, as the case may be, to the Holder. If the Holder and the Company are unable to agree upon such determination or calculation of the Exercise Price or the Warrant Shares within three Business Days of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall, within two (2) Business Days submit via facsimile or electronic mail (a) the disputed determination of the Exercise Price to an independent, reputable investment bank selected by the Company and approved by the Holder or (b) the disputed arithmetic calculation of the Warrant Shares to the Company's independent, outside accountant. The Company shall cause at its expense the investment bank or the accountant, as the case may be, to perform the determinations or calculations and notify the Company and the Holder of the results no later than ten Business Days from the time it receives the disputed determinations or calculations. Such investment bank's or accountant's determination or calculation, as the case may be, shall be binding upon all parties absent demonstrable error.

14. REMEDIES, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual damages for any failure by the Company to comply with the terms of this Warrant.

15. TRANSFER. This Warrant may not be offered for sale, sold, transferred or assigned prior to the Exercise Date. Thereafter, subject to compliance with any applicable securities laws, this Warrant may be offered for sale, sold, transferred or assigned without the consent of the Company.

16. CERTAIN DEFINITIONS. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "**Bloomberg**" means Bloomberg Financial Markets.

(b) "**Business Day**" "Business Day" means any day on which both (a) the Common Stock is scheduled to trade for at least 4.5 hours on the Principal Market and (b) the Transfer Agent is open for business.

(c) "**Closing Bid Price**" and "**Closing Sale Price**" means, for any security as of any date, the last closing bid price and last closing trade price, respectively, for such security on the Principal Market, as reported by Bloomberg, or, if the Principal Market begins to operate on an extended hours basis and does not designate the closing bid price or the closing trade price, as the case may be, then the last bid price or the last trade price, respectively, of such security prior to 4:00:00 p.m., New York time, as reported by Bloomberg, or, if the Principal Market is not the principal securities exchange or trading market for such security, the last closing bid price or last trade price, respectively, of such security on the principal securities exchange or trading market where such security is listed or traded as reported by Bloomberg, or if the foregoing do not apply, the last closing bid price or last trade price, respectively, of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg, or, if no closing bid price or last trade price, respectively, is reported for such security by Bloomberg, the average of the bid prices, or the ask prices, respectively, of any market makers for such security as reported by OTC Link LLC (formerly Pink OTC Markets Inc.). If the Closing Bid Price or the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Bid Price or the Closing Sale Price, as the case may be, of such security on such date shall be the fair market value as determined by the Board of Directors of the Company in the exercise of its good faith judgment. All such determinations to be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

(d) "**Common Stock**" means (i) the Company's shares of Common Stock, par value $0.001 per share, and (ii) any share capital into which such Common Stock shall have been changed or any share capital resulting from a reclassification of such Common Stock.

(e) "**Convertible Securities**" means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for shares of Common Stock.

(f) "**Eligible Market**" means the Principal Market, The New York Stock Exchange, Inc., The American Stock Exchange, The NASDAQ Global Select Market or The NASDAQ Capital Market.

(g) "**Expiration Date**" means the tenth anniversary date of the effective date of the Collaboration Agreement or, if such date falls on a day other than a Business Day or on which trading does not take place on the Principal Market (a "**Holiday**"), the next date that is not a Holiday; **except** as otherwise provided in Section 5.D(i) of the Collaboration Agreement upon a material breach by Battelle thereunder.

(h) "**Fundamental Transaction**" means that the Company shall, directly or indirectly, in one or more related transactions, (i) consolidate or merge with or into (whether or not the Company is the surviving corporation) another Person, or (ii) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of the Company to another Person, or (iii) allow another Person to make a purchase, tender or exchange offer that is accepted by the holders of more than the 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the Person or Persons making or party to, or associated or affiliated with the Persons making or party to, such purchase, tender or exchange offer), or (iv) consummate a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock purchase agreement or other business combination), (v) reorganize, recapitalize or reclassify its Common Stock, or (vi) any "person" or "group" (as these terms are used for purposes of Sections 13(d) and 14(d) of the Exchange Act) is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding Common Stock.

(i) "**Options**" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

(j) "**Parent Entity**" of a Person means an entity that, directly or indirectly, controls the applicable Person and whose common stock or equivalent equity security is quoted or listed on an Eligible Market, or, if there is more than one such Person or Parent Entity, the Person or Parent Entity with the largest public market capitalization as of the date of consummation of the Fundamental Transaction.

(k) "**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity and a government or any department or agency thereof.

(l) "**Principal Market**" means The NASDAQ Capital Market or the principal securities exchange or other securities market on which the Common Stock is being traded at any time.

(m) "**Successor Entity**" means the Person (or, if so elected by the Holder, the Parent Entity) formed by, resulting from or surviving any Fundamental Transaction or the Person (or, if so elected by the Holder, the Parent Entity) with which such Fundamental Transaction shall have been entered into.

(n) "**Trading Day**" means any day on which the Common Stock are traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock are then traded; *provided* that "Trading Day" shall not include any day on which the Common Stock are scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock are suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York time).

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out above.

DISCOVERY LABORATORIES, INC.

By: /s/ John Tattory
Name: John Tattory
Title: Senior Vice President and Chief Financial Officer

EXHIBIT A

EXERCISE NOTICE

TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS WARRANT TO PURCHASE COMMON STOCK

DISCOVERY LABORATORIES, INC.

The undersigned holder hereby exercises the right to purchase _____ of the shares of Common Stock ("**Warrant Shares**") of Discovery Laboratories, Inc, a Delaware corporation (the "**Company**"), evidenced by the attached Warrant to Purchase Common Stock (the "**Warrant**"). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Form of Exercise Price. The Holder intends that payment of the Exercise Price shall be made as:

_____ a "Cash Exercise" with respect to _____ Warrant Shares; and/or

_____ a "Cashless Exercise" with respect to _____ Warrant Shares.

2. Payment of Exercise Price. In the event that the holder has elected a Cash Exercise with respect to some or all of the Warrant Shares to be issued pursuant hereto, the holder shall pay the Aggregate Exercise Price in the sum of $_____ to the Company in accordance with the terms of the Warrant.

3. Delivery of Warrant Shares. The Company shall deliver _____ Warrant Shares in the name of the undersigned holder or in the name of _____ in accordance with the terms of the Warrant to the following DWAC Account Number or by physical delivery of a certificate to:

_____

_____

_____

Date: _____ __, _____

_____
Name of Registered Holder

By: _____
Name:
Title:

EXHIBIT B

ASSIGNMENT FORM

(To assign the foregoing warrant, execute
this form and supply required information.
Do not use this form to exercise the warrant.)

FOR VALUE RECEIVED, [____] all of or [_____] shares of the foregoing Warrant and all rights evidenced thereby are hereby assigned to

_____ whose address is

_____.

_____

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

_____

Signature Guaranteed: _____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank or trust company. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

Exhibit 4.12

THIS WARRANT AND ANY SECURITIES ACQUIRED UPON THE EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE, AND MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND APPLICABLE STATE SECURITIES LAWS OR PURSUANT TO AN APPLICABLE EXEMPTION TO THE REGISTRATION REQUIREMENTS OF SUCH ACT AND SUCH LAWS. THIS WARRANT AND SUCH SECURITIES MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF EXCEPT IN COMPLIANCE WITH THE CONDITIONS SPECIFIED HEREIN.

DISCOVERY LABORATORIES, INC.

FORM OF WARRANT TO PURCHASE COMMON STOCK

Warrant No.: BMI00002
Number of Shares of Common Stock: 500,000
Date of Issuance: October 10, 2014 ("**Issuance Date**")

Discovery Laboratories, Inc., a Delaware corporation (the "**Company**"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, **Battelle Memorial Institute** ("**Battelle**"), the registered holder hereof or its permitted assigns (the "**Holder**"), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "**Warrant**"), at any time or times on or after the Exercise Date (defined below), but not after 11:59 p.m., New York time, on the Expiration Date (defined below), Five Hundred Thousand (500,000) fully paid nonassessable shares of Common Stock (as defined below) (the "**Warrant Shares**"). This Warrant is issued in conjunction with that certain Collaboration Agreement (the "**Collaboration Agreement**") by and between the Company and Battelle, dated October 10, 2014, entered into in conjunction herewith. Except as otherwise defined herein, capitalized terms in this Warrant shall have the meanings set forth in Section 16.

1. EXERCISE OF WARRANT.

(a) Mechanics of Exercise. Subject to the terms and conditions hereof, this Warrant may be exercised by the Holder on any day on or after the date on which Battelle shall have achieved the Device Development Milestone (as that term is defined in the Collaboration Agreement), provided that such date occurs on or before the Milestone Date (as that term is defined in the Collaboration Agreement) (the "**Exercise Date**"), in whole or in part, upon (i) surrender of this Warrant, with a notice in the form attached hereto as Exhibit A (the "**Exercise Notice**"), duly completed and executed by an authorized officer of the Holder, together with such evidence of authority as the Company may reasonably request, and (ii) (A) payment of the Exercise Price multiplied by the number of Warrant Shares as to which this Warrant is being exercised (the "**Aggregate Exercise Price**") in cash or by wire transfer of immediately available funds or (B) provided the conditions for cashless exercise set forth in Section 1(d) are satisfied, by notifying the Company that this Warrant is being exercised pursuant to a Cashless Exercise (as defined in Section 1(d)); at the office of the Company, 2600 Kelly Road, Suite 100, Warrington, PA 18976, Phone: (215) 488-9300, Fax: (215) 488-9421, electronic mail (Warrants@discoverylabs.com). On or before the third (3rd) Business Day (the "**Share Delivery Date**") following the date on which the Company has received each of the Exercise Notice and the Aggregate Exercise Price (or notice of a Cashless Exercise) (collectively, the "**Exercise Documents**"), the Company shall (X) provided that Continental Stock Transfer & Trust Company (the Company's "**Transfer Agent**") is participating in The Depository Trust Company ("**DTC**") Fast Automated Securities Transfer Program, upon the request of the Holder, credit such aggregate number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit/Withdrawal At Custodian ("**DWAC**") system, or (Y) if the Transfer Agent is not participating in the DTC Fast Automated Securities Transfer Program or the Holder does not request delivery of the Warrant Shares via DWAC, issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise. Upon delivery of the Exercise Documents, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or delivered in certificate form, as the case may be. If this Warrant is submitted to exercise a number of Warrant Shares in connection with any exercise and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the number of Warrant Shares being acquired upon an exercise, then the Company shall as soon as practicable and in no event later than three Business Days after any exercise and at its own expense, issue a new Warrant (in accordance with Section 8(d)) representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, reduced by the number of Warrant Shares being exercised. No fractional shares of Common Stock are to be issued upon the exercise of this Warrant, but rather the number of shares of Common Stock to be issued shall be rounded down to the nearest whole number. The Company shall pay any and all taxes which may be payable with respect to the issuance and delivery of Warrant Shares upon a partial exercise of this Warrant.

(b) Exercise Price. For purposes of this Warrant, "**Exercise Price**" means $5.00, subject to adjustment as provided herein.

(c) Company's Failure to Timely Deliver Securities. If the Company shall fail for any reason or for no reason to issue to the Holder within three (3) Business Days of receipt of the Exercise Documents in compliance with the terms of this Section 1, a certificate for the number of shares of Common Stock to which the Holder is entitled and register such shares of Common Stock on the Company's share register or to credit the Holder's balance account with DTC for such number of shares of Common Stock to which the Holder is entitled upon the Holder's exercise of this Warrant, and if on or after such Trading Day the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of shares of Common Stock issuable upon such exercise that the Holder anticipated receiving from the Company (a **"Buy-In"**), then the Company shall, within three (3) Business Days after the Holder's request, (1) pay cash to the Holder in the amount by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased in the Buy-in, exceeds (y) the amount obtained by multiplying (A) the number of Warrant Shares that the Company has failed to deliver in connection with the exercise, by (B) the price at which the sell order giving rise to the Buy-in was executed; and (2) at the option of the Holder, either (xx) provided that a registration statement covering the issuance of the Warrant Shares that are the subject of the Exercise Notice is effective, deliver to the Holder the number of Warrant Shares that would have been issued had the Company timely complied with the Exercise Notice and its delivery obligations hereunder, or (yy) provided the conditions for cashless exercise set forth in Section 1(d) are satisfied, notify the Company that the Warrant should be exercised pursuant to a Cashless Exercise (as defined in Section 1(d)), or (zz) reinstate that portion of the Warrant and equivalent number of Warrant Shares that the Company failed to deliver (prior to receipt by the Holder of the Exercise Shares),

(d) Cashless Exercise. Notwithstanding anything contained herein to the contrary, if, but only if, a registration statement covering the issuance of the Warrant Shares that are the subject of the Exercise Notice (the "**Unavailable Warrant Shares**") is not effective and an exemption from registration for the issuance and resale of such Unavailable Warrant Shares would only be available if the exercise of the Warrant were effected pursuant to a Cashless Exercise in accordance with this Section 1(d), then the Holder may exercise this Warrant in whole or in part and, in lieu of making the cash payment upon such exercise in payment of the Aggregate Exercise Price, elect instead to receive upon such exercise the "Net Number" of shares of Common Stock determined according to the following formula (a "**Cashless Exercise**"):

$$\text{Net Number} = \frac{(A \times B) - (A \times C)}{B}$$

For purposes of the foregoing formula:

A= the total number of shares with respect to which this Warrant is then being exercised.

B= the arithmetic average of the Closing Sale Prices of the shares of Common Stock for the five (5) consecutive Trading Days ending on the Trading Day immediately preceding the date of the Exercise Notice.

C= the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For sake of clarity, in the event that neither a registration statement nor an exemption from registration is available, there is no circumstance that would require the Company to effect a net cash settlement of the Warrants.

(e) Rule 144. For purposes of Rule 144(d) promulgated under the Securities Act of 1934 (the "**Securities Act**"), as in effect on the date hereof, it is intended that the Warrant Shares issued in a Cashless Exercise shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued pursuant to the Underwriting Agreement.

(f) Disputes. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed, and all such disputes shall be resolved pursuant to Section 13.

(g) Beneficial Ownership. The Company shall not effect the exercise of this Warrant, and the Holder shall not have the right to exercise this Warrant, to the extent that after giving effect to such exercise, such Person (for the purpose of this clause (g), together with such Person's affiliates) would beneficially own in excess of 9.99% (the "**Maximum Percentage**") of the shares of Common Stock outstanding immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by such Person and its affiliates shall include the number of shares of Common Stock of this Warrant being exercised, but shall exclude shares of Common Stock issuable upon (i) exercise of any unexercised portion of this Warrant beneficially owned by such Person and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by such Person (including, without limitation, any convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein. Except as set forth in the preceding sentence, for purposes of this paragraph, beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended. For purposes of this Warrant, in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (1) the Company's most recent public filing with the Securities and Exchange Commission, (2) a more recent public announcement by the Company or (3) any notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. To the extent that the limitation contained in this Section 1(g) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of an Exercise Notice shall be deemed to be each Holder's determination of whether this Warrant is exercisable and which portion of this Warrant is exercisable, and the Company shall have no obligation to verify or confirm the accuracy of such determination. For any reason at any time, upon the written or oral request of the Holder, the Company shall within two (2) Business Days confirm to the Holder the number of shares of Common Stock then outstanding. This Section 1(g) shall be construed and implemented in a manner otherwise than in strict conformity with its terms to correct this paragraph or any portion of this paragraph which may be defective or inconsistent with the intended beneficial ownership limitation or to make changes or supplements necessary or desirable to properly give effect to such limitation.

2. ADJUSTMENT OF EXERCISE PRICE AND NUMBER OF WARRANT SHARES. The Exercise Price and the number of Warrant Shares shall be adjusted from time to time as follows:

(a) Adjustment upon Subdivision or Combination of Common Stock. If the Company at any time on or after the Issuance Date subdivides (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise) one or more classes of its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced and the number of Warrant Shares will be proportionately increased. If the Company at any time on or after the Pricing Date combines (by any stock split, stock dividend, recapitalization, reorganization, scheme, arrangement or otherwise) one or more classes of its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination will be proportionately increased and the number of Warrant Shares will be proportionately decreased. Any adjustment under this Section 2(a) shall become effective at the close of business on the date the subdivision or combination becomes effective.

(b) Other Events. If any event occurs of the type contemplated by the provisions of this Section 2 but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features), then the Company's Board of Directors will make an appropriate adjustment in the Exercise Price and the number of Warrant Shares so as to protect the rights of the Holder; provided that no such adjustment pursuant to this Section 2(b) will increase the Exercise Price or decrease the number of Warrant Shares as otherwise determined pursuant to this Section 2.

3. RIGHTS UPON DISTRIBUTION OF ASSETS. If the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to all holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "**Distribution**"), at any time after the issuance of this Warrant, then, in each such case:

(a) any Exercise Price in effect immediately prior to the close of business on the record date fixed for the determination of holders of shares of Common Stock entitled to receive the Distribution shall be reduced, effective as of the close of business on such record date, to a price determined by multiplying such Exercise Price by a fraction of which (i) the numerator shall be the Closing Bid Price of the shares of Common Stock on the Trading Day immediately preceding such record date minus the value of the Distribution (as determined in good faith by the Company's Board of Directors) applicable to one share of Common Stock, and (ii) the denominator shall be the Closing Bid Price of the shares of Common Stock on the Trading Day immediately preceding such record date; and

(b) the number of Warrant Shares shall be increased to a number of shares equal to the number of shares of Common Stock obtainable immediately prior to the close of business on the record date fixed for the determination of holders of shares of Common Stock entitled to receive the Distribution multiplied by the reciprocal of the fraction set forth in the immediately preceding paragraph (a); *provided* that in the event that the Distribution is of shares of Common Stock (or common stock) ("**Other Shares of Common Stock**") of a company whose shares of common stock are traded on a national securities exchange or a national automated quotation system, then the Holder may elect to receive a warrant to purchase Other Shares of Common Stock in lieu of an increase in the number of Warrant Shares, the terms of which shall be identical to those of this Warrant, except that such warrant shall be exercisable into the number of shares of Other Shares of Common Stock that would have been payable to the Holder pursuant to the Distribution had the Holder exercised this Warrant immediately prior to such record date and with an aggregate exercise price equal to the product of the amount by which the exercise price of this Warrant was decreased with respect to the Distribution pursuant to the terms of the immediately preceding paragraph (a) and the number of Warrant Shares calculated in accordance with the first part of this paragraph (b).

4. PURCHASE RIGHTS; FUNDAMENTAL TRANSACTIONS.

(a) Purchase Rights. In addition to any adjustments pursuant to Section 2 above, if at any time the Company grants, issues or sells any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "**Purchase Rights**"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights.

(b) Fundamental Transactions. The Company shall not enter into or be party to a Fundamental Transaction unless the Successor Entity assumes this Warrant in accordance with the provisions of this Section (4)(b), including agreements to deliver to each holder of Warrants in exchange for such Warrants a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant, including, without limitation, an adjusted exercise price equal to the value for the shares of Common Stock reflected by the terms of such Fundamental Transaction, and exercisable for a corresponding number of shares of capital stock equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and satisfactory to the Holder. Upon the occurrence of any Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein. Upon consummation of the Fundamental Transaction, the Successor Entity shall deliver to the Holder confirmation that there shall be issued upon exercise of this Warrant at any time after the consummation of the Fundamental Transaction, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property) purchasable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had this Warrant been converted immediately prior to such Fundamental Transaction, as adjusted in accordance with the provisions of this Warrant. In addition to and not in substitution for any other rights hereunder, prior to the consummation of any Fundamental Transaction pursuant to which holders of shares of Common Stock are entitled to receive securities or other assets with respect to or in exchange for shares of Common Stock (a "**Corporate Event**"), the Company shall make appropriate provision to insure that the Holder will thereafter have the right to receive upon an exercise of this Warrant at any time after the consummation of the Fundamental Transaction but prior to the Expiration Date, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property) purchasable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had the Warrant been exercised immediately prior to such Fundamental Transaction. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The provisions of this Section 4 shall apply similarly and equally to successive Fundamental Transactions and Corporate Events and shall be applied without regard to any limitations on the exercise of this Warrant.

5. NONCIRCUMVENTION. The Company hereby covenants and agrees that the Company will not, by amendment of its Certificate of Incorporation, Bylaws or through any reorganization, transfer of assets, consolidation, merger, scheme of arrangement, dissolution, issue or sale of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, and will at all times in good faith carry out all the provisions of this Warrant and take all action as may be required to protect the rights of the Holder. Without limiting the generality of the foregoing, the Company (i) shall not increase the par value of any shares of Common Stock receivable upon the exercise of this Warrant above the Exercise Price then in effect, (ii) shall take all such actions as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable shares of Common Stock upon the exercise of this Warrant, and (iii) shall, so long as this Warrant is outstanding, take all action necessary to reserve and keep available out of its authorized and unissued shares of Common Stock, solely for the purpose of effecting the exercise of this Warrant, 100% of the number of shares of Common Stock issuable upon exercise of this Warrant then outstanding (without regard to any limitations on exercise).

6. PRIVATE PLACEMENT; REGISTRATION RIGHTS

(a) Private Placement Representations. The Holder represents that it is an "accredited investor" within the meaning of Regulation D under the Securities Act who is acquiring the Warrants without having been offered or sold the Warrant by any form of "general solicitation" or "general advertising", in each case within the meaning of Regulation D under the Securities Act, and that the Warrants are being or will be acquired for its own account or for one or more separate accounts maintained by it or for the account of one or more pension or trust funds and not with a view toward distributing or reselling such securities or any part thereof in any transaction that would be in violation of the Securities Act, federal securities laws or the securities laws of any state, without prejudice, however, to its rights to sell or otherwise dispose of all or any part of the Warrants under an effective registration statement under the Securities Act and applicable state securities laws, or under an exemption from such registration available under the Securities Act and applicable state securities laws.

(b) Private Offering by the Company. Neither the Company nor anyone acting on its behalf has offered the Warrants for sale to, or solicited any offer to buy any of the same from, or otherwise approached or negotiated in respect thereof with, any person other than the Holders, each of which has been offered the Warrants at a private sale for investment. Neither the Company nor anyone acting on its behalf has taken, or will take, any action that would subject the issuance or sale of the Warrants to the registration requirements of section 5 of the Securities Act or to the registration requirements of any securities or blue sky laws of any applicable jurisdiction.

(c) Restrictive Legends. Each certificate for Warrant Shares issued upon the exercise of the Warrant, and each certificate issued upon the transfer of any such Warrant Shares, shall be stamped or otherwise imprinted with a legend in substantially the following form:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE, AND MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND APPLICABLE STATE SECURITIES LAWS OR PURSUANT TO AN APPLICABLE EXEMPTION TO THE REGISTRATION REQUIREMENTS OF SUCH ACT AND SUCH LAWS."

(d) Registration Rights. The Company and Holder shall negotiate in good faith and, prior to the Exercise Date, enter into a customary registration rights agreement providing for registration rights and procedures relating thereto that are mutually agreeable by the parties acting in good faith with respect to the Warrant Shares that Holder has the right to acquire pursuant the exercise of this Warrant.

7. WARRANT HOLDER NOT DEEMED A STOCKHOLDER. Except as otherwise specifically provided herein, the Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

8. REISSUANCE OF WARRANTS.

(a) Transfer of Warrant. If this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company together with a written assignment of this Warrant in the form attached hereto as Exhibit B duly executed by an authorized officer of the Holder or its agent or attorney, together with such evidence of authority as the Company may reasonably request, whereupon the Company will forthwith, subject to compliance with any applicable securities laws, issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 8(d)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 8(d)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred.

(b) Lost, Stolen or Mutilated Warrant. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary form and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company shall execute and deliver to the Holder a new Warrant (in accordance with Section 8(d)) representing the right to purchase the Warrant Shares then underlying this Warrant.

(c) Exchangeable for Multiple Warrants. This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company, for a new Warrant or Warrants (in accordance with Section 8(d)) representing in the aggregate the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; provided, however, that no Warrants for fractional shares of Common Stock shall be given.

(d) Issuance of New Warrants. Whenever the Company is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant (i) shall be of like tenor with this Warrant, (ii) shall represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Section 8(a) or Section 8(c), the Warrant Shares designated by the Holder which, when added to the number of shares of Common Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) shall have an issuance date, as indicated on the face of such new Warrant, which is the same as the Issuance Date, and (iv) shall have the same rights and conditions as this Warrant.

9. NOTICES. The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Warrant, including in reasonable detail a description of such action and the reason therefor. Whenever notice is required to be given under this Warrant, unless otherwise provided herein, such notice shall be given in writing, will be mailed (a) if within the domestic United States by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, or by facsimile or (b) if delivered from outside the United States, by International Federal Express or facsimile, and (c) will be deemed given (i) if delivered by first-class registered or certified mail domestic, three business days after so mailed, (ii) if delivered by nationally recognized overnight carrier, one business day after so mailed, (iii) if delivered by International Federal Express, two business days after so mailed and (iv) if delivered by facsimile, upon electronic confirmation of receipt, and will be delivered and addressed as follows:

(a) if to the Company, to:

Discovery Laboratories, Inc.
2600 Kelly Road
Warrington, Pennsylvania 18976
Attention: Chief Financial Officer
Facsimile: 215-488-9301

with copies to:

Discovery Laboratories, Inc.
2600 Kelly Road
Warrington, Pennsylvania 18976
Attention: General Counsel
Facsimile: 215-488-9557

(b) if to the Holder, at its address on the Exercise Notice in the form attached as Exhibit A hereto, or at such other address or addresses as may have been furnished to the Company in writing to the foregoing addresses.

10. AMENDMENT AND WAIVER. Except as otherwise provided herein, the provisions of this Warrant may be amended only with the written consent of the Company and the Holder, and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only with the written consent of the Holder.

11. GOVERNING LAW. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of Delaware, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Delaware or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Delaware.

12. CONSTRUCTION; HEADINGS. This Warrant shall be deemed to be jointly drafted by the Company and the Holder and shall not be construed against any person as the drafter hereof. The headings of this Warrant are for convenience of reference and shall not form part of, or affect the interpretation of, this Warrant.

13. DISPUTE RESOLUTION. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall submit the disputed determinations or arithmetic calculations via facsimile or electronic mail within two (2) Business Days of receipt of the Exercise Notice giving rise to such dispute, as the case may be, to the Holder. If the Holder and the Company are unable to agree upon such determination or calculation of the Exercise Price or the Warrant Shares within three Business Days of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall, within two (2) Business Days submit via facsimile or electronic mail (a) the disputed determination of the Exercise Price to an independent, reputable investment bank selected by the Company and approved by the Holder or (b) the disputed arithmetic calculation of the Warrant Shares to the Company's independent, outside accountant. The Company shall cause at its expense the investment bank or the accountant, as the case may be, to perform the determinations or calculations and notify the Company and the Holder of the results no later than ten Business Days from the time it receives the disputed determinations or calculations. Such investment bank's or accountant's determination or calculation, as the case may be, shall be binding upon all parties absent demonstrable error.

14. REMEDIES, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual damages for any failure by the Company to comply with the terms of this Warrant.

15. TRANSFER. This Warrant may not be offered for sale, sold, transferred or assigned prior to the Exercise Date. Thereafter, subject to compliance with any applicable securities laws, this Warrant may be offered for sale, sold, transferred or assigned without the consent of the Company.

16. CERTAIN DEFINITIONS. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "**Bloomberg**" means Bloomberg Financial Markets.

(b) "**Business Day**" "Business Day" means any day on which both (a) the Common Stock is scheduled to trade for at least 4.5 hours on the Principal Market and (b) the Transfer Agent is open for business.

(c) "**Closing Bid Price**" and "**Closing Sale Price**" means, for any security as of any date, the last closing bid price and last closing trade price, respectively, for such security on the Principal Market, as reported by Bloomberg, or, if the Principal Market begins to operate on an extended hours basis and does not designate the closing bid price or the closing trade price, as the case may be, then the last bid price or the last trade price, respectively, of such security prior to 4:00:00 p.m., New York time, as reported by Bloomberg, or, if the Principal Market is not the principal securities exchange or trading market for such security, the last closing bid price or last trade price, respectively, of such security on the principal securities exchange or trading market where such security is listed or traded as reported by Bloomberg, or if the foregoing do not apply, the last closing bid price or last trade price, respectively, of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg, or, if no closing bid price or last trade price, respectively, is reported for such security by Bloomberg, the average of the bid prices, or the ask prices, respectively, of any market makers for such security as reported by OTC Link LLC (formerly Pink OTC Markets Inc.). If the Closing Bid Price or the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Bid Price or the Closing Sale Price, as the case may be, of such security on such date shall be the fair market value as determined by the Board of Directors of the Company in the exercise of its good faith judgment. All such determinations to be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

(d) "**Common Stock**" means (i) the Company's shares of Common Stock, par value $0.001 per share, and (ii) any share capital into which such Common Stock shall have been changed or any share capital resulting from a reclassification of such Common Stock.

(e) "**Convertible Securities**" means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for shares of Common Stock.

(f) "**Eligible Market**" means the Principal Market, The New York Stock Exchange, Inc., The American Stock Exchange, The NASDAQ Global Select Market or The NASDAQ Capital Market.

(g) "**Expiration Date**" means the tenth anniversary date of the effective date of the Collaboration Agreement or, if such date falls on a day other than a Business Day or on which trading does not take place on the Principal Market (a "**Holiday**"), the next date that is not a Holiday; **except** (i) upon a material breach by Battelle of its obligations under the Collaboration Agreement, then this warrant shall expire immediately as provided in Section 5.D(i) of the Collaboration Agreement, and (ii) if the Exercise Date shall not have occurred on or before the Milestone Date provided in Section 3.E.ii. of the Collaboration Agreement, then this Warrant shall expire on the last day of the month in which the Milestone Date occurs.

(h) "**Fundamental Transaction**" means that the Company shall, directly or indirectly, in one or more related transactions, (i) consolidate or merge with or into (whether or not the Company is the surviving corporation) another Person, or (ii) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of the Company to another Person, or (iii) allow another Person to make a purchase, tender or exchange offer that is accepted by the holders of more than the 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the Person or Persons making or party to, or associated or affiliated with the Persons making or party to, such purchase, tender or exchange offer), or (iv) consummate a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock purchase agreement or other business combination), (v) reorganize, recapitalize or reclassify its Common Stock, or (vi) any "person" or "group" (as these terms are used for purposes of Sections 13(d) and 14(d) of the Exchange Act) is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding Common Stock.

(i) "**Options**" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

(j) "**Parent Entity**" of a Person means an entity that, directly or indirectly, controls the applicable Person and whose common stock or equivalent equity security is quoted or listed on an Eligible Market, or, if there is more than one such Person or Parent Entity, the Person or Parent Entity with the largest public market capitalization as of the date of consummation of the Fundamental Transaction.

(k) "**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity and a government or any department or agency thereof.

(l) "**Principal Market**" means The NASDAQ Capital Market or the principal securities exchange or other securities market on which the Common Stock is being traded at any time.

(m) "**Successor Entity**" means the Person (or, if so elected by the Holder, the Parent Entity) formed by, resulting from or surviving any Fundamental Transaction or the Person (or, if so elected by the Holder, the Parent Entity) with which such Fundamental Transaction shall have been entered into.

(n) "**Trading Day**" means any day on which the Common Stock are traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock are then traded; *provided* that "Trading Day" shall not include any day on which the Common Stock are scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock are suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York time).

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out above.

DISCOVERY LABORATORIES, INC.

By: /s/ John Tattory
Name: John Tattory
Title: Senior Vice President and Chief Financial Officer

EXHIBIT A

EXERCISE NOTICE

TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS WARRANT TO PURCHASE COMMON STOCK

DISCOVERY LABORATORIES, INC.

The undersigned holder hereby exercises the right to purchase _____ of the shares of Common Stock ("**Warrant Shares**") of Discovery Laboratories, Inc, a Delaware corporation (the "**Company**"), evidenced by the attached Warrant to Purchase Common Stock (the "**Warrant**"). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Form of Exercise Price. The Holder intends that payment of the Exercise Price shall be made as:

_____ a "Cash Exercise" with respect to _____ Warrant Shares; and/or

_____ a "Cashless Exercise" with respect to _____ Warrant Shares.

2. Payment of Exercise Price. In the event that the holder has elected a Cash Exercise with respect to some or all of the Warrant Shares to be issued pursuant hereto, the holder shall pay the Aggregate Exercise Price in the sum of $_____ to the Company in accordance with the terms of the Warrant.

3. Delivery of Warrant Shares. The Company shall deliver _____ Warrant Shares in the name of the undersigned holder or in the name of _____ in accordance with the terms of the Warrant to the following DWAC Account Number or by physical delivery of a certificate to:

_____
_____
_____

Date: _____ __, _____

_____
Name of Registered Holder

By: _____
Name:
Title:

EXHIBIT B

ASSIGNMENT FORM

(To assign the foregoing warrant, execute
this form and supply required information.
Do not use this form to exercise the warrant.)

FOR VALUE RECEIVED, [____] all of or [_____] shares of the foregoing Warrant and all rights evidenced thereby are hereby assigned to

_____ whose address is

_____.

_____

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

_____

Signature Guaranteed: _____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank or trust company. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

Exhibit 10.1

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 24b-2 under the Exchange Act of 1934, as amended. Confidential Portions are marked: [***]

COLLABORATION AGREEMENT

BETWEEN

DISCOVERY LABORATORIES, INC.,

AND

BATTELLE MEMORIAL INSTITUTE

REGARDING

DEVELOPMENT OF AEROSURF®

Dated as of October 10, 2014

TABLE OF CONTENTS

COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (the "Agreement") is made and entered into by and between DISCOVERY LABORATORIES, INC., a corporation organized and existing under the laws of the state of Delaware having its principal place of business at 2600 Kelly Road, Suite 100, Warrington, PA 18976 USA ("Discovery Labs"), and BATTELLE MEMORIAL INSTITUTE, through its Corporate Operations, a corporation organized and existing under the laws of the state of Ohio having its principal place of business at 505 King Avenue, Columbus, Ohio 43201-2693, USA ("Battelle") as of October 10, 2014 (the "Effective Date"). Discovery Labs and Battelle may be referred to herein individually as a "Party" or collectively as "Parties".

RECITALS:

WHEREAS, Discovery Labs is developing AEROSURF® as a therapy for premature infants with respiratory distress syndrome ("RDS"). AEROSURF is an investigational combination drug/device product that combines Discovery Labs' proprietary technologies: lyophilized synthetic KL4 surfactant for inhalation and its capillary aerosol generator (CAG). By enabling delivery of aerosolized lyophilized KL4 surfactant using less invasive procedures, Discovery Labs believes that AEROSURF will address a serious unmet medical need and enable the treatment of a significantly greater number of premature infants with RDS; and

WHEREAS, over the past two years, Discovery Labs has engaged Battelle to assist in developing the CAG aerosol technology and to manufacture aerosol devices and accompanying disposables that meet the requirements for the AEROSURF phase 2 clinical program. To date, the developmental device and disposables have been deployed in a clinical trial setting in several neonatal intensive care units (NICU's) in the US. The current developmental device and disposable units are expected to be utilized in a planned phase 2b study; and

WHEREAS, further investment in development of the developmental device and disposable units will be required to continue the AEROSURF clinical program into phase 3 and potential commercialization, and the Parties are interested in collaborating to further develop Discovery Labs' CAG technology into a product that will meet the requirements for a phase 3 clinical trial and commercialization of AEROSURF (the "Collaboration");

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

1. DEFINITIONS.

Except as otherwise defined herein, the following terms shall have the meanings described below:

A. “AEROSURF” means Discovery Labs’ investigational combination drug/device product that combines Discovery Labs’ proprietary technologies: lyophilized synthetic KL4 surfactant for inhalation and its capillary aerosol generator (CAG). For the purposes of this Agreement, “AEROSURF” means AEROSURF for the treatment of respiratory distress syndrome (RDS) in premature infants.

B. “AEROSURF System” means that particular system described in the Product Requirements Document, being developed for use in the treatment of respiratory distress syndrome (RDS) in premature infants.

C. "Affiliates" means with respect to any Party, any entity who directly or indirectly Controls, or is Controlled by, or is under common Control with such Party. Affiliates include subsidiaries. The term Affiliate or Affiliates, as to Battelle, does not include any person or business operation which manages or operates national laboratories, other laboratories of a third party, or facilities for any of the United States of America, foreign governments or entities, or a third party.

D. “Commercially Reasonable Efforts” means the level of efforts and resources, and the application of the requisite level of skills and experience, commonly used in the medical device industry by a company of similar size and with similar capital resources to the Party with respect to the development and commercialization of a product of similar commercial potential at a similar stage in its development or product life, taking into consideration its safety and efficacy, its cost to develop, manufacture and bring to market, the prevalence of the therapeutic purpose for which it is intended, the competitiveness of alternative devices or systems, the patent and other proprietary position of such device or system, the likelihood of regulatory approval, market size and geographic dispersion, product sales cycle, and its profitability.

E. "Consumables" means disposable dose packet, including a capillary element and other materials that may be included as part of the AEROSURF System as to be detailed in the PRD.

F. “Control” means (a) with respect to any item of Confidential Information (as such term is further defined in the CDA), patent, know how or other intellectual property right, the right to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with, or any legal rights of, any third party, or (b) with respect to any specified party, the possession, directly or indirectly, of the power to direct the management or policies of such party, whether through the ownership of voting equity or by contract relating to voting rights or corporate governance, or otherwise.

G. “Cost Overruns” means any expenses incurred by Battelle that exceed the sum of the Project Plan Fixed Cost and the planned costs set forth in all associated Scope Change Orders.

H. “Device Development Milestone” means successful completion by Battelle of Stage 3 activities as set forth in the Project Plan.

I. "Discovery Labs Fixed Fee" means the fixed fee payable by Discovery Labs to Battelle for Battelle's performance and completion of Stages 2 and 3 of the Project Plan, which amount may be subject to amendment following completion of Stage 1 Work, as provided in Section 3.B(i).

J. "Discovery Labs Default Percent" means, at any time, that portion of the Project Plan performed by Battelle up to the date of termination for material breach by Discovery Labs, expressed as a percent equal to the percentage of the aggregate Discovery Labs Fixed Fee invoiced by Battelle to Discovery Labs up to the date of such termination, plus any amount not yet invoiced by Battelle for the period from the date of the last invoice through the date of such termination [***].

K. "First Commercial Sale" occurs on the date following Registration of AEROSURF in the Territory on which (i) Discovery Labs, an Affiliate or a sublicensee sells AEROSURF (whether based on the AEROSURF System or any Next Generation System(s)), to a non-Affiliate and (ii) Discovery Labs or an Affiliate records Net Sales or Net License Revenues in accordance with U.S. (or other applicable) generally accepted accounting principles ("GAAP"), consistently applied.

L. "Net License Revenues" means royalties actually received by Discovery Labs or an Affiliate from third-party licensees or sublicensees on account of commercial sales of AEROSURF (whether based on the AEROSURF System or any Next Generation System(s)), including sales of related AEROSURF Consumables, in the Territory in accordance with terms and conditions of the applicable licensing or sublicensing agreement. For monies received by Discovery Labs or an Affiliate in a currency other than U.S. dollars, the monies shall be converted to U.S. dollars based on a commercially reasonable method in the industry then used by Discovery Labs in the preparation of its audited financial statements, consistently applied.

M. "Net Sales" means the amount recognized by Discovery Labs or an Affiliate, in accordance with U.S. GAAP (or by an Affiliate in accordance with applicable GAAP), representing the gross amount invoiced by Discovery Labs or an Affiliate as a result of arms-length, commercial transactions in the Territory on account of the sale of AEROSURF (whether based on the AEROSURF System or any Next Generation System(s)), including the sale of related AEROSURF Consumables [***], less all amounts customarily excluded from the calculation of net sales by Discovery Labs or its Affiliate, including by way of example, [***]. For sales denominated in a currency other than U.S. dollars, the sales shall be converted to U.S. dollars based on a commercially reasonable method in the industry then used by Discovery Labs in the preparation of its audited financial statements, consistently applied.

N. "Next Generation System" means any drug-device combination product or medical device, which (i) essentially and in all material respects utilizes, incorporates, derives from, are made using or based on the AEROSURF System for the treatment of RDS in premature infants developed by Battelle under this Agreement, or (ii) [***].

O. “Product Requirements Document” or “PRD” shall mean the detailed device requirements for the AEROSURF System and assumptions and data supplied by Discovery Labs to Battelle, and which is included in the Project Plan.

P. “Project” means the project as more particularly identified in the Project Plan.

Q. “Project Managers” refers to the individuals designated by each of Discovery Labs and Battelle from time to time to manage the overall coordination of the Project.

R. “Project Plan” means the confidential plan attached to this Agreement as Schedule 1, which includes the PRD and identifies appropriate steps contemplated for both Parties and key milestones contemplated to complete development of a device for use in Discovery Labs’ planned phase 3 AEROSURF clinical program and, if AEROSURF is Registered, initial commercialization of AEROSURF, and the related timeline, costs and expenses to complete Stages 1 through 3 of the Project, together.

S. “Project Plan Fixed Cost” means the fixed investment amount established by the Parties to fund Stages 2 and 3 of the Project Plan, which may be adjusted after completion of Stage 1 Work. Project Plan Fixed Cost will be used solely to determine the Discovery Labs Fixed Fee, as more particularly set forth in Section 3.B(i).

T. “Registration” or “Register” means obtaining permissions, authorizations, registrations or approvals from the U.S. Food and Drug Administration (“FDA”), the European Commission (“EU”) or other applicable regulatory authorities, as necessary to manufacture, use, commercialize and/or sell AEROSURF (or other combination drug/device product comprised of a Next Generation System and Discovery Labs’ lyophilized KL4 surfactant for inhalation for the treatment of RDS in premature infants) in the Territory.

U. “Royalty Cap” means the aggregate maximum royalties to be paid by Discovery Labs to Battelle for performance of its obligations under the Project Plan during the Term of this Agreement. The amount of the Royalty Cap is set forth in Section 3.D(ii).

V. “Scope Change” means a change in the scope of the Product Requirements Document, including any assumptions and intentions of the Parties contained therein.

W. “Scope Change Order” means a written modification to this Project Plan agreed to and signed by both Parties reflecting the terms of a Scope Change.

X. “Services Agreement” means the Research and Development Services Agreement entered into between the Parties on June 22, 2012, as amended from time to time.

Y. “Stage 1 Work” means the initial work performed hereunder as agreed by the Parties, which is expected to result in a final, agreed Project Plan and which will be funded according to the terms of Section 3.A of this Agreement.

Z. “Territory” means all countries worldwide.

Unless otherwise defined, all references in this Agreement to sections and clauses refer to sections and clauses in this Agreement.

2. IMPLEMENTATION OF THE PROJECT.

A. General Scope.

This Agreement is in addition to, and not in substitution of, the Services Agreement, which covered work on aspects of the AEROSURF program. Any activities that are ongoing under the Services Agreement and any future proposals included under the Services Agreement by amendment shall be performed in accordance with the terms of the Services Agreement. The activities as defined in the Project Plan of this Agreement are required to further the AEROSURF program and will be performed under the terms of this Agreement.

The general scope of activities under this Agreement will include a three-stage Project Plan which, at a high level, shall consist of an initial stage to define the requirements of the AEROSURF System (Stage 1 Work), Stage 2, which will be devoted to Phase 3 device and disposables development ("Device Development") and Stage 3, which will complete all testing and verification to be in a position to manufacture AEROSURF System(s) for use in Discovery Labs' phase 3 clinical program and, if approved, initial commercial supply. The Parties also may agree from time to time to amend this Agreement to expand the scope or include other projects under this Agreement and will also enter into such other agreements as they deem necessary or appropriate to meet the objectives of this Agreement, including but not limited to a Quality Agreement. Upon completion of the Project Plan, the Parties intend to negotiate in good faith to enter into an agreement covering the manufacture of AEROSURF Systems, including AEROSURF Consumables, for use in the AEROSURF phase 3 clinical program. The Parties contemplate that, if AEROSURF is approved, they will negotiate in good faith to enter into a supply agreement providing for initial commercial supply.

B. Battelle's Contribution to the Project.

i. Battelle will use Commercially Reasonable Efforts to:

a. perform research and development services according to the Project Plan, and to meet the milestones according to the Project Plan and to otherwise perform its obligations pursuant to the Project Plan and under this Agreement. Battelle further agrees to exercise Commercially Reasonable Efforts to meet objectives and comply with directions and guidance with respect to the Project Plan, the PRD, and any Scope Change Order, that may be established from time to time by the Steering Committee or Discovery Labs, as appropriate, and to promptly and thoroughly inform the Steering Committee of the status of development efforts under this Agreement and the Project Plan; and

b. contribute, in accordance with the terms of this Agreement, its labor costs and expenses necessary to complete the work under the Project Plan, in exchange for the payments and other compensation provided by Discovery Labs in accordance with Section 3 herein.

C. Discovery Lab's Contribution to the Project.

i. Discovery Labs will use Commercially Reasonable Efforts to:

a. perform its obligations set forth in the Project Plan;
b. adhere to all provisions of this Agreement; and
c. if Discovery Labs' clinical program achieves the desired results and if Discovery Labs successfully Registers AEROSURF in the U.S. for the treatment of RDS in premature infants, provide for the U.S. commercial launch of AEROSURF (based on the AEROSURF System or a Next-Generation System) following Registration in the U.S.; and perform or provide for all necessary marketing and sales activities to support the distribution of AEROSURF in the U.S. for the duration of the Agreement. Such activities may include, but shall not be limited to, adhering to Registration requirements in the U.S., conducting or providing for the manufacture of devices and drug product, and conducting or providing for marketing, selling, distribution and warranty of AEROSURF.

ii. Discovery Labs shall compensate Battelle according to the terms of Section 3.

D. Scope Change Orders.

i. Following agreement on a final Project Plan at the completion of Stage 1 Work, the Parties may enter into a Scope Change Order for the purpose of (a) incorporating the final Project Plan in this Agreement, (b) adjusting the Project Plan Fixed Cost and the associated Discovery Labs Fixed Fee based on the results of Stage 1 Work, and (c) incorporating such other changes that the Parties agree are necessary and appropriate.

ii. In addition, it may be necessary during the performance of the Project Plan, to enter into one or more additional Scope Change Orders to implement changes determined by Discovery Labs as being necessary or appropriate under the circumstances to meet its objectives. In that event, the Parties will negotiate in good faith to agree upon an appropriate cost and implementation plan for such Scope Change and enter into a Scope Change Order. To the extent that implementation of a Scope Change, as set forth in the related Scope Change Order, causes the date for completion of the Project Plan to be extended beyond the then current Milestone Date (as defined in Section 3.E(ii), below), then such Milestone Date shall be delayed for the period of such extension. By way of example, if implementation of a Scope Change Order would cause the Project Plan to be extended by one month, then the Milestone Date would be similarly extended to June 30, 2016.

E. Establishing Project Managers.

i. Each Party shall appoint an individual to serve as such Party's Project Manager, who shall be responsible for the day to day management of the Project and communications with the other Party and the Steering Committee, as may be appropriate to advance the purposes of this Agreement.

ii. Project Managers and their respective teams will be in frequent communications and contact as required to perform the Project Plan.

iii. Project Managers shall keep up to date, and otherwise maintain, the Project Plan, including, if appropriate, forecasts for Project spending, and will provide periodic updates, in such form as is acceptable to the Steering Committee.

iv. Each Project Manager will immediately notify the other of any event which is likely to substantially affect the Project or the timely completion of the Device Development Milestone.

v. The Parties will appoint initial Project Managers within 72 hours of the Effective Date. Each Party shall appoint and replace its Project Manager as it deems appropriate during the term of this Agreement. When possible, a Party will allow for a minimum of a week's transition if it elects to appoint a new Project Manager.

F. Establishing the Steering Committee.

i. Membership. The Steering Committee shall initially consist of a maximum of six members, with an even number of members from each Party, with all initial members to be appointed within fourteen calendar days after the Effective Date. A Discovery Labs member will serve as Chairman of the Steering Committee. The Chairman shall be responsible for scheduling special meetings, circulating the agenda and presiding as chair at each meeting. The size of the Steering Committee can be amended upon mutual agreement of the Parties. Each Party shall appoint and replace its representatives to the Steering Committee as it deems appropriate during the term of this Agreement.

ii. Meetings. During the period beginning with the Effective Date through the completion of Stage 3, the Steering Committee will meet in-person at a minimum of once each calendar quarter according to a schedule agreed by the Parties. After that period of time, in-person meetings shall be held as requested by a Party on no less than three (3) business days' advance notice (unless such notice is waived by all members). A majority of members must be present or otherwise available for a meeting to be constituted. Each Party may appoint a replacement or delegate for any member who is unable to attend a meeting of the Steering Committee. The location for each in-person meeting will alternate between Columbus, Ohio and Warrington, Pennsylvania. Each Party will bear its own expenses to prepare for and attend in-person Steering Committee meetings and these shall not be considered Project-related expenses for any purpose. The Steering Committee may conduct meetings (other than in-person meetings) by telephone or video conference and may act without a meeting by written consent signed by both Parties. Both Parties may contribute to the agenda for any upcoming Steering Committee meeting and meeting minutes must be taken during every meeting, however held. All such minutes and other records of the Steering Committee shall be available at all times to either Party. Employees of each Party who are not on the Steering Committee or delegates of a Party may attend meetings of the Steering Committee, as required to further the Project. Neither Party shall be entitled to instruct its representatives to refuse to attend or to convene any properly noticed and scheduled meeting as a means of avoiding the establishment of a quorum, and a deemed quorum shall exist if a Party shall fail for any reason to have its representatives in attendance (in person or by telephone or video conference) more than twice at any properly noticed and scheduled (or adjourned) meeting. The Steering Committee will establish such standing rules as it deems appropriate to conduct its work, to the extent that such rules are not inconsistent with this Agreement.

iii. At each quarterly meeting, and otherwise as needed, the Steering Committee will:
   a. Require members to indicate whether their respective Parties are pursuing the Project Plan in compliance with this Agreement;
   b. Hear updates on the Project Plan from the Project Managers;
   c. Evaluate the progress made since the date of the prior meeting and approve the results of the Project to date, in writing;
   d. Discuss and decide any issues brought to its attention by the Project Managers including without limitation those brought under Section 3 and Section 9.E or which a member of the Steering Committee wishes to raise; and
   e. Discuss and decide how to proceed with the Project if the Steering Committee does not approve the results to date.

G. Decision Making Generally.

i. For the duration of the Project, the Project Managers may resolve issues that arise in day-to-day operations under the Project Plan unless otherwise stated in this Section.

ii. The Steering Committee shall be responsible for resolving outstanding issues regarding the following:
   a. Any day-to-day issue or other matter that Project Managers cannot decide;
   b. Any and all changes in Project Plan dates and the Product Requirements Document and any updates or amendments thereto; and
   c. All other matters of any kind brought to its attention by a Party.

iii. The Steering Committee will use Commercially Reasonable Efforts to reach consensus on all matters before it. The Steering Committee will duly consider the input of the Project Managers in reaching its decisions. If the Steering Committee is unable to reach consensus on any matter within a reasonable time under the circumstances, either Party may escalate the matter in accordance with the terms of Section 6(A)(viii) (Dispute Resolution).

iv. Notwithstanding the foregoing, Discovery Labs shall have final decision-making authority and the final say on all matters relating to the design, Registration, manufacture, packaging, marketing, distribution and sale of the AEROSURF System, and any final decision made by Discovery Labs on such matters shall not be subject to any further review under the dispute resolution provisions of Section 6.A(ix) of this Agreement or in any court or other forum either at law or in equity.

3. COMPENSATION TO BATTELLE.

A. Stage 1 Work.

With respect solely to Stage 1 Work, Discovery Labs will pay Battelle fifty percent (50%) of Battelle's costs and expenses incurred, including Cost Overruns and Scope Changes, according to [***] invoices prepared by Battelle for all Stage 1 Work performed by Battelle under the Project Plan. Based on an estimated cost for Stage 1 Work of approximately [***], Discovery Labs expects that its share of Stage 1 Work will be approximately [***]. Battelle Invoices will indicate all costs incurred by Battelle for Stage 1 Work performed, and Battelle will provide further detail [***], through [***] detailed project plan reports. Discovery Labs shall pay all Battelle invoices in accordance with Section 3.C.

B. Stages 2 – 3 Work.

i. Discovery Labs Fixed Fee. The estimated Project Plan Fixed Cost as of the Effective Date is [***]. The estimated Discovery Labs Fixed Fee as of the Effective date is 50% of the Project Plan Fixed Cost, or [***]. The Project Plan Fixed Cost may be revised once by mutual agreement of the Parties following completion of the Stage 1 Work, to take into account any increase or decrease in anticipated costs of the Project Plan based on the results of the Stage 1 Work. If the Project Plan Fixed Cost is revised, the Discovery Labs Fixed Fee will be similarly revised to equal 50% of the revised Project Plan Fixed Cost. [***]. Battelle shall be solely responsible for any and all Cost Overruns related to its performance of its obligations under the Project Plan.

ii. Scope Changes. Discovery Labs shall be responsible for any increase in the Project Plan costs that result from Scope Changes detailed in Scope Change Orders approved under Section 2.D(ii). The Parties shall agree to [***]. In addition, [***], the Parties shall agree to [***]. Battelle shall be responsible for any Cost Overruns associated with any Scope Changes affecting Stages 2 and 3.

iii. Stages 2 – 3 Work Invoices. Discovery Labs Fixed Fee shall be payable in [***] over the period of performance set forth in the final Project Plan established following the Stage 1 Work. Battelle shall prepare [***] invoices, each of which shall reflect the Discovery Labs Fixed Fee [***] amount due, [***]. The [***] detailed project plan report shall also include such other information as may be agreed by the Parties.

iv. Detailed Project Plan Report. In addition, invoices shall be accompanied by a detailed report of actual work performed by Battelle in performing its obligations under the Project Plan, and, for Stage 1 Work, shall include [***].

v. Taxes. For all payments hereunder, [***] shall pay any [***], or similar taxes arising out of or in connection with the performance of this Agreement (other than those [***]), imposed by any authority, government or governmental agency, unless a valid exemption certificate, if applicable, is received. [***] shall be responsible for taxes based on [***].

C. Payment of Invoices; Financial Covenant.

i. Under no circumstances shall the amount payable by Discovery Labs for Battelle's performance under the Project Plan exceed the sum of the Discovery Labs Fixed Fee plus, [***] Scope Change Orders approved under Section 2.D(ii).

ii. [***] invoiced amounts shall be payable on a date no later than [***].

iii. All payments made to Battelle under this Agreement shall be in U.S. dollars and shall be made without reduction for, or withholding of, any tax assessment, fee, levy, or similar charge in lieu of tax of any nature, by bank wire transfer in immediately available funds to an account designated by Battelle.

iv. Discovery Labs shall maintain at all times aggregate available cash and cash equivalents (as reflected in its financial statements) sufficient to satisfy the amounts that would be due Battelle if invoices were [***]. If as of the last business day of a calendar quarter, any Battelle invoices to Discovery Labs are outstanding [***].

D. Royalties.

i. As consideration for Battelle's achievement of the Device Development Milestone, Discovery Labs will pay royalties to Battelle in an amount equal to [***] of Net Sales and Net License Revenues in the Territory. Royalty payments based on Net Sales or Net License Revenues in the U.S. shall be made [***]. Royalty payments based on Net Sales or Net License Revenues outside the U.S. shall be made [***].

ii. The payment of royalties by Discovery Labs to Battelle shall be subject to a Royalty Cap of Twenty Five Million dollars ($25,000,000). Upon payment of aggregate royalties equal to the Royalty Cap, Discovery Labs obligations to pay royalties under this Section 3.D shall terminate.

E. Warrants.

i. As consideration for Battelle's investment in the Project under this Agreement, on the Effective Date, Discovery Labs shall execute and deliver to Battelle a warrant, in the form of Exhibit A (the "Initial Warrant"), granting Battelle the right to purchase One Million (1.00M) shares of Discovery Labs common stock, par value $0.001 per share ("Common Stock"), at an exercise price per share equal to Five Dollars ($5.00), exercisable upon achievement of the Device Development Milestone, and expiring on the tenth anniversary date of the Effective Date.

ii. As consideration for the achievement of the Device Development Milestone on or before May 31, 2016 ("Milestone Date"), or such later date as may be determined under Section 2.D(ii), on the Effective Date, Discovery Labs will execute and deliver to Battelle a second Warrant, in the form of Exhibit B, granting Battelle the right to purchase 500,000 shares of Common Stock, at an exercise price per share equal to Five Dollars ($5.00), exercisable upon achievement of the Device Development Milestone, provided such event occurs no later than the Milestone Date, and expiring on the tenth anniversary date of the Effective Date.

4. SALES REPORTS, RECORD KEEPING AND AUDITS.

A. Battelle Records. Battelle shall keep complete, true and accurate books of account and records for the purpose of determining Stage 1 Work [***] invoices to be delivered by Battelle to Discovery Labs under this Agreement. Such books and records relating to all costs billed to Discovery Labs shall be kept at the principal place of business of Battelle or at such reasonably accessible location acceptable to Discovery Labs, as the case may be, [***] following the end of the [***] period to which they pertain. Such records, excluding Battelle's proprietary indirect rates and their associated calculations, will be open for inspection during such [***] period by a public accounting firm to whom Battelle has no reasonable objection. Such inspections may be made no more than [***], at reasonable times, on reasonable notice and at Discovery Labs' expense which shall include Battelle's direct costs, including labor costs, in providing for such an audit. Any under- or over-payment that is discovered shall be promptly reconciled.

B. Discovery Labs Reports. Beginning [***] with respect to which the first royalty payment to Battelle is made, Discovery Labs shall provide written reports [***] with respect to Net Sales and Net License Revenues in the U.S., and [***] with respect to Net Sales and Net License Revenues from outside the U.S., and shall state in each such report, separately for Discovery Labs, Affiliates and each sublicensee, the number, description, and aggregate Net Sales and Net License Revenues, by region, sold during [***].

C. Discovery Labs Records. Discovery Labs and its agents shall keep complete, true and accurate books of account and records for the purpose of determining the payments to be made to Battelle under this Agreement. Such books and records shall be kept at Discovery Labs' principal place of business for [***] following the end of [***] to which they pertain. Such records will be open for inspection during such [***] period by a public accounting firm to whom Discovery Labs has no reasonable objection, solely for the purpose of verifying payment obligations hereunder. Such inspections may be made no more than [***], at reasonable times, on reasonable notice and at Battelle's expense. Any under- or over-payment that is discovered shall be promptly reconciled.

5. TERM AND TERMINATION.

A. Term. This Agreement shall have a term ("Term") that shall begin as of the Effective Date and expire upon the fulfillment of all payment obligations of Discovery Labs to Battelle under this Agreement, unless sooner terminated as provided in this Section 5.

B. Bankruptcy.

With respect to bankruptcy or insolvency, if a Party shall:

i. admit in writing its inability to pay its debts generally as they become due;
ii. file a petition in bankruptcy or a petition to take advantage of any insolvency act which are not be dismissed within [***] after the filing thereof;
iii. make an assignment for the benefit of creditors;

iv. consent to the appointment of a receiver of the whole or any substantial part of its property;
v. on a petition in bankruptcy filed against it, be adjudicated a bankrupt, which is not dismissed within [***] after the filing thereof;
vi. file a petition or answer seeking reorganization or similar arrangement under applicable law;
vii. if a court of competent jurisdiction shall enter an order, judgment, or decree appointing, without the consent of the Party, a receiver of the whole or any substantial part of the Party's property, and such order, judgment or decree shall not be vacated or set aside or stayed within [***] from the date of entry thereof; or
viii. if, under the provisions of any other law for the relief or aid of debtors, any court of competent jurisdiction shall assume custody or control of the whole or any substantial part of a Party's property and such custody or control shall not be terminated or stayed within [***] from the date of assumption of such custody or control,

then, for any of the foregoing scenarios, the other Party shall have the right to terminate this Agreement upon [***] written notice to the Party subject to such circumstances.

C. ‘Failure of Purpose’ Termination Rights.

Either Party may terminate this Agreement on thirty (30) calendar days’ written notice to the other Party upon the occurrence of one or more of the following events (each, a “Failure of Purpose”):

i. After a good faith negotiation, the Parties fail to agree on a final Project Plan within [***] of the Stage 1 Work;
ii. Discovery Labs determines in good faith that (a) the AEROSURF clinical program (including with respect thereto, related preclinical studies) has failed or will fail to demonstrate the results needed to proceed with the AEROSURF development program based on the AEROSURF System, or (b) Discovery Labs is unable to achieve Registration of AEROSURF in the U.S.;
iii. After consultation, the Parties determine in good faith that, for reasons other than a material breach by a Party, the Project Plan cannot be completed for the reason of technical infeasibility;
iv. After consultation with Battelle, Discovery Labs determines in good faith that, for reasons other than a material breach by a Party, the Parties will be unable to complete the Project Plan within [***] after the then-current Milestone Date; or
v. Extended Force Majeure exceeding six months.

Other than as specifically set forth in this Agreement, including Discovery Labs’ obligation to pay Battelle invoices, [***]; provided that, if Discovery Labs terminates this Agreement pursuant to Clause (ii) of this Section 5.C after Battelle has successfully completed Stage 3, and if Discovery Labs or an Affiliate subsequently Registers AEROSURF based on the AEROSURF System developed by Battelle in the Territory [***], then Discovery Labs or an Affiliate [***] provided in Section 3.D(ii).

D. Termination for Breach.

If either Party believes the other is in material breach of its obligations under this Agreement, including failure to pay an undisputed amount due under this Agreement, it may give notice of such breach or payment failure to the other Party, which Party shall have thirty (30) calendar days after receipt of such notice in which to remedy such breach. If such alleged breach is not remedied in the time period set forth above, the non-breaching Party may terminate this Agreement and receive the liquidated damages set forth below, as their respective sole and exclusive monetary remedy, which liquidated damages are agreed in light of the difficulty in forecasting damages as of the Effective Date. Nothing in the foregoing shall preclude equitable remedies in addition to monetary remedies.

i. In the event Discovery Labs terminates this Agreement because of an uncured material breach by Battelle:
   a. Discovery Labs' obligation to pay royalties to Battelle shall cease;
   b. any outstanding warrants delivered to Battelle pursuant to this Agreement shall expire immediately and be of no further effect;
   c. At its expense, Battelle shall cooperate with Discovery Labs to complete the activities provided in Section 5.F; and
   d. Battelle shall pay to Discovery Labs within [***] (after receipt of an invoice from Discovery Labs) [***] of the amount paid by Discovery Labs to Battelle under Section 3 of this Agreement up to the effective date of termination, plus reasonable costs to cover transition to a successor.

ii. In the event Battelle terminates this Agreement because of an uncured material breach by Discovery Labs:
   a. Discovery Labs shall pay to Battelle all outstanding amounts then due from Discovery Labs under this Agreement, including unpaid invoiced amounts, and reasonable transition costs [***];
   b. Discovery Labs shall pay to Battelle within [***] (after receipt of an invoice from Battelle) [***] of the amount of the Project Plan Fixed Cost actually contributed by Battelle under the Project Plan up to the effective date of termination;
   c. if Discovery Labs or an Affiliate (i) completes the Project Plan without the assistance of Battelle, and (ii) [***]; and
   d. that percent of the Initial Warrant issued to Battelle on the Effective Date that equals the Discovery Labs Default Percent shall immediately become exercisable and remain outstanding for the period therein provided.

E. Section 365(n) of the Bankruptcy Code.

All grants, rights and licenses granted or created under or pursuant to this Agreement by Discovery Labs or Battelle are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the Party hereto that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non- subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

F. Post-Termination Activities.

In the event that either Party issues a notice of termination of this Agreement, the Parties will exercise Commercially Reasonable Efforts during the [***] period following issuance by a Party of such notice of termination to reach agreement regarding an appropriate wind-down plan, taking into account ethical responsibilities to patients in clinical trials (if any), control of any trailing project costs, and the stewardship of intellectual property and other assets created by the Parties hereunder. Battelle shall promptly transfer or return to Discovery Labs all data, reports, materials, Discovery Labs Inventions, designs, models, working embodiments, prototypes etc. of the device, and must take continuing action to disclose and transfer the know-how and technical information relating to the Project to Discovery Labs and to cooperate and take measures to assign to Discovery Labs and execute such documents as Discovery Labs may reasonably request to perfect Discovery Labs' title as sole owner of all Discovery Labs' Inventions. Except as provided in Section 5.D(i), Discovery Labs shall pay Battelle's reasonable expenses in complying with this Section 5.F. Battelle shall issue to Discovery Labs detailed invoices in a manner consistent with those prepared for Stage 1 Work described in Section 3.A.

6. TERMS AND CONDITIONS INCORPORATED BY REFERENCE.

A. The following provisions of the Services Agreement are incorporated herein by reference, provided that references in the Services Agreement to "Agreement", "Project", "Services" and other defined terms shall be construed to refer to such terms as defined in this Agreement or, if not so defined, in a manner to be consistent with the terms and conditions of this Agreement:

i.	Section 3	Intellectual Property
ii.	Section 4	No Endorsement: Public Announcement
iii.	Section 5	Confidentiality (excluding Section 5.3)
iv.	Section 7	Warranties; Limitation of Liability (excluding Section 7.2)
v.	Section 8	Indemnities
vi.	Section 13	U.S. Export Control
vii.	Section 14	Client Furnished Materials
viii.	Section 16	Dispute Resolution

B. [***].

C. Discovery Labs assumes responsibility for its use, misuse, or inability to use the Project results, except to the extent of liabilities resulting from the gross negligence or willful misconduct of Battelle. Except as necessary to satisfy Third Party Claims (as defined in Section 8.1 of the Services Agreement) indemnified hereunder, [***], Battelle's total liability to Discovery Labs arising out of or related to this Agreement [***]. Except for a breach of Section 6.B or its confidentiality obligations hereunder and as set forth in the CDA, neither Party shall be liable to the other Party for any indirect, incidental, consequential, special, punitive or exemplary damages in connection with this Agreement or the Project, however caused, under any theory of liability. [***].

7. **INSURANCE**

Discovery Labs shall purchase and maintain, at its own expense, insurance in amounts reasonable and customary for the industry in which they operate. Discovery Labs shall maintain all insurance which is required by any law, statute, ordinance or regulation of any jurisdiction having authority in whole or in part over their operations. Nevertheless, the following minimum insurance coverage shall be maintained:

a. Clinical Trials Insurance: If any AEROSURF System or Next Generation System developed under this Agreement is used by Discovery Labs in clinical trial(s), prior to the first activity involving human subjects, Discovery Labs shall maintain no less than [***] of clinical trials liability insurance related to the AEROSURF System or Next Generation System in all territories (on a country-by-country basis) in which the Device is used in clinical trials involving human subjects.
b. Product Liability Insurance: Prior to the commercial sale of any AEROSURF System or Next Generation System, Discovery Labs shall maintain no less than [***] of product liability insurance related to the AEROSURF System or Next Generation System in all territories (on a country-by-country basis) in which the Device is commercially available. Such insurance shall cover any Discovery Labs products that may be developed in whole or in part based on Battelle's work under this Agreement and shall name Battelle Memorial Institute as an additional insured.

Discovery Labs shall maintain coverage with insurance companies that [***]. Should any of the insurance policies agreed to herein provide coverage on a claims-made basis, such insurance shall be kept in force for a period of [***]. Discovery Labs shall provide a certificate of insurance to Battelle evidencing such coverage prior to the first administration to a human subject of such product and prior to the sale of such product. Such certificate shall provide that, if a policy is cancelled, notice will be delivered as provided in the policy provisions. Discovery Labs shall use commercially reasonable efforts to provide at least thirty (30) days prior notice to Battelle of any cancellation, non-renewal, or relevant reduction in coverage.

8. REPRESENTATIONS AND WARRANTIES OF THE PARTIES.

Battelle and Discovery Labs each hereby represent and warrant to each other, as of the Effective Date, as set forth below:

i. It is duly organized and validly existing and in good standing under the laws of its jurisdiction of incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

ii. It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder.

iii. Its legal team (i) is not aware of any pending or threatened litigation involving the AEROSURF System and (ii) has not received any communications alleging that it has violated or would violate any rights (including intellectual property rights) of any third party; in each case, which if decided adversely, would reasonably be expected to have a material adverse effect upon such Party, its condition, financial or otherwise, or its business affairs or business prospects, or its ability to perform its obligations under this Agreement.

iv. To its knowledge, there is no material unauthorized use, infringement or misappropriation of any of its patents, copyrights, trademarks, trade secret rights or know-how necessary or useful to make, use or sell the AEROSURF System.

v. All of its employees, officers, contractors and consultants performing research and development services related to this Agreement have executed agreements requiring assignment to the Party of all inventions made during the course of and as a result of their association with such Party and obligating the individual to maintain as confidential the Confidential Information of such Party.

vi. It has the power, authority and legal right, and is free to enter into this Agreement and, in so doing, will not violate any other agreement to which it is a party as of the Effective Date.

vii. Battelle represents and warrants that, after due inquiry, it has not and will not knowingly employ, contract with or retain any person directly or indirectly to perform services under this Agreement, if such person is debarred by the FDA under 21 USC 335a(k) of the FDA Act or a regulator in the EU under similar laws. Upon written request from Discovery Labs, Battelle shall within five (5) business days confirm in writing that it has complied with the foregoing obligation.

viii. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not and will not, whether with the giving of notice or passage of time or both, conflict with or violate any requirement of any obligation, agreement, covenant or condition contained in any contract, indenture, credit agreement, or other agreement or instrument to which it is a party ("Agreements/Instruments"), (b) nor will such actions result in any violation of any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party, as applicable, (c) nor will such actions result in any violation of any applicable law, statute, rule, regulation, judgment, order, writ or decree of any government, government instrumentality or court, domestic or foreign, having jurisdiction over the Company or any Affiliate or any of their assets, properties or operations; do not conflict with, violate, or breach or constitute a default or require any consent under, any applicable law or any Agreements/Instruments or court or administrative order by which such Party is bound; except, with respect to each of the foregoing clauses viii(a)-(c), for those or under those circumstances that would not reasonably be expected to have a material adverse effect upon such Party, its condition, financial or otherwise, or its business affairs or business prospects, or its ability to perform its obligations under this Agreement.

ix. Battelle acknowledges that the success of the Project Plan, and the efforts by Discovery Labs to secure Registration, and execute a commercial launch for, AEROSURF in the U.S. are subject to a variety of risks and uncertainties that could cause results to differ materially from those set forth in the Project Plan or otherwise anticipated by the Parties. Examples of such risks and uncertainties are set forth in Discovery Labs' Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission ("SEC") on March 15, 2014 and in Discovery Labs' periodic and other reports filed with the SEC from time to time.

x. Discovery Labs acknowledges that its business strategy includes seeking to enter into a significant strategic alliance that potentially could provide development, regulatory and commercial market expertise as well as financial resources for the AEROSURF development program, and, if AEROSURF is approved, support the commercial introduction of AEROSURF and/or AEROSURF System(s) in the EU and other selected markets outside the U.S. However, there can be no assurance that Discovery Labs will succeed, if at all, during the performance of this Agreement.

With respect to the foregoing, the term "knowledge" shall be deemed to refer to the personal knowledge of the respective Parties management and the legal team

9. MISCELLANEOUS.

A. Assignment. Except as otherwise provided for herein, neither Party may assign this Agreement without the written consent of the other Party, which consent may be granted or withheld in the other Party's sole discretion. Notwithstanding the foregoing, [***]. In any event, this Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 8(A) shall be void.

B. Compliance with Law. The Parties shall comply with appropriate legal, ethical and professional standards of behavior and conduct, and will exercise diligence in complying with all laws applicable to their relationship and to each Party's performance as described herein, including, but not limited to, the following U.S. laws: Foreign Corrupt Practices Act, the Export Administration Act, the Export Administration Regulations including the Anti-boycott Regulations and Guidelines, and any other applicable export regulations.

C. Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be effective on receipt, when sent via Internet email, hand-delivered, transmitted by facsimile, or sent by registered airmail or overnight courier and addressed to the Parties as noted below (or to such other address as may be provided in writing by a Party to the other Party in accordance with this Section).

For Battelle: Battelle Memorial Institute
Attn: General Counsel 505 King Avenue
Columbus, Ohio 43201

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

D. Severability. If any part of this Agreement is found to be invalid or unenforceable by any court of competent jurisdiction, or if any government or other agency having jurisdiction over either Battelle or Discovery Labs deems any part thereof to be contrary to any antitrust or competition law, then such declaration shall not affect the remainder of the Agreement, which shall remain in full force and effect. To the extent possible, the Parties shall revise such invalidated part in a manner that will render it valid without impairing the Parties' original business purpose.

E. Force Majeure. Except as otherwise provided herein, no Party shall be in breach of this Agreement, or liable to the other Party, for any loss, damages, delay or failure of performance to the extent such loss, damages, delay or failure is caused by circumstances beyond its reasonable control. Circumstances beyond the reasonable control of a Party include, but are not limited to, fire, strikes, riots, wars, terroristic acts, martial law, extreme natural disaster, or threat of terroristic acts, embargoes, shortages, delays in transportation, environmental contamination by nuclear fuel or nuclear waste, inability to obtain supplies of raw materials or requirements or regulations of any government or any other civil or military authority. In the event of a force majeure situation, the obligations of the Parties under this Agreement shall be suspended as long as the force majeure situation continues. Should the force majeure situation continue for more than four (4) weeks, then the Steering Committee will make appropriate determinations of the effect of the force majeure on the contractual relationship between the Parties.

F. Non-Waiver. The failure of a Party in any one or more instances to insist upon strict performance of any of the terms and conditions of this Agreement shall not be construed as a waiver or relinquishment, to any extent, of the right to assert or rely upon any such terms or conditions on any future occasion.

G. Disclaimer of Agency. Battelle's relationship with Discovery Labs is that of an independent Contractor and not as an agent, representative, or employee of Discovery Labs. This Agreement shall not constitute, create or give effect to, or otherwise imply a joint venture, corporation, partnership, or any other form of business entity of any kind. Each Party to this Agreement shall act as an independent contractor with respect to the other Party. Neither Party to this Agreement shall have any authority or control over the other Party or the other Party's employees, nor shall either Party have the power to bind the other Party, nor shall this Agreement be construed as creating any actual or implied authority or any type of agency relationship.

In addition, Discovery Labs specifically acknowledges that Battelle is a service provider and contract manufacturer and not a distributor or supplier and Discovery Labs retains all final decision making authority and all responsibility for the design, manufacture, packaging, marketing, distribution and sale of the AEROSURF System, including, without limitation, product labeling, warnings, and instructions to users.

H. Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

I. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

J. Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of and enforced within the jurisdiction of the State of Delaware without regard to the principles of conflict of laws.

K. Entire Agreement; Amendment. This Agreement, the Exhibits attached hereto, and together with the Services Agreement, the CDA, and any Quality Agreement between the Parties, sets forth the terms of the agreement regarding AEROSURF System between the Parties hereto and, except for the CDA incorporated therein, the Quality Agreement and as otherwise set forth herein, supersedes and terminates all prior representations, term sheets, agreements and understandings between the Parties regarding the subject matter hereof. No alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

L. Survival. The following provisions shall survive the termination or expiration of this Agreement: 3, 4, 5, 6(A)(i), 6(A)(iii)-(v), 6(A)(viii), 6(B), 6(C), 7, and 9(J).

[Signatures appear on the next page]

In Witness Whereof, the Parties have duly executed this Collaboration Agreement as of the Effective Date.

DISCOVERY LABORATORIES, INC.	**BATTELLE MEMORIAL INSTITUTE** **Corporate Operations**
By:	By:
Name: John G. Cooper	Name:
Title: President and Chief Executive Officer	Title:

Proposal No. [***]

Next-Generation Aerosurf® Delivery System, Stage 1

Prepared by

Battelle
505 King Avenue
Columbus, Ohio 43201

Prepared for

Lawrence Weinstein
Vice President, Medical Device Development
Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976-3622
October 9, 2014

Exhibit 31.1

CERTIFICATIONS

I, John G. Cooper, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: November 7, 2014

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

Exhibit 31.2

CERTIFICATIONS

I, John Tattory, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: November 7, 2014

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

Exhibit 32.1

CERTIFICATIONS

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

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

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

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

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