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, 2013
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 November 8, 2013, 80,749,022 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

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PART I - FINANCIAL INFORMATION

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

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements represent only our current expectations about future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "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 for which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans and our expectations and timing related to commercialization of SURFAXIN®, the AFECTAIR® device for infants and our products under development, if approved; our research and development programs, including planning for development activities, anticipated timing of clinical trials and potential development milestones; plans for the manufacture of drug products, active pharmaceutical ingredients (APIs) and materials and medical devices; and plans regarding potential strategic alliances and other collaborative arrangements to develop, manufacture and market our products.

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

- risks relating to the ability of our sales and marketing organization to effectively introduce SURFAXIN in the U.S. and, if approved, our other product candidates, in a timely manner, if at all; and that we may not succeed in developing a 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, if we fail to successfully commercialize SURFAXIN as planned, and if we do not achieve revenues consistent with our expectations, our revenues would be limited, and we may be unable to secure additional capital when needed, 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;

- the risks that, although the U.S. Food and Drug Administration (FDA) has completed its review and cleared our investigational new drug (IND) application for our AEROSURF® phase 2 clinical program, and we expect to initiate our phase 2 clinical program in the fourth quarter of 2013, our clinical program may be delayed, or fail, which will harm our business;

- 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 KL_4 surfactant pipeline products, beginning with AEROSURF (our combination drug-device product based on our aerosolized KL_4 surfactant and our capillary aerosol generator (CAG) technology that we are developing to address RDS in premature infants), and including the development of our lyophilized KL_4 surfactant, and, if approved, commercialization of AEROSURF in markets outside the U.S.; and 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 research and development activities, which among other things involve time-consuming and expensive preclinical studies and potentially multiple clinical trials that may be subject to potentially significant delays or regulatory holds or fail;

- risks related to our efforts to gain regulatory approval, in the U.S. and elsewhere, for our drug product and medical device candidates, including AEROSURF, a drug-device combination product that we are developing to address RDS in premature infants, and our lyophilized KL4 surfactant that we expect will be the drug component of AEROSURF and potentially be developed as a life cycle extension of SURFAXIN under the name SURFAXIN LS™ ;

- 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 must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for both commercial and research and development activities;

- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems or delays in manufacturing our KL4 surfactant drug products and the APIs used in the manufacture of our drug product, CAG devices and other materials on a timely basis or in an amount sufficient to support the commercial introduction of SURFAXIN and the AFECTAIR device for infants, our aerosol-conducting airway connector, as well as our research and development activities for AEROSURF and our other product candidates;

- the risks that, even if we succeed with the commercial introduction of SURFAXIN, we nevertheless in the future will require, but may be unable to secure, significant additional capital to continue our operations, fund our debt service and support our research and development activities 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;

- risks relating to our pledge of substantially all of our assets to secure our obligations under our loan facility (Deerfield Facility) with 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 15, 2013, 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 device technology companies have suffered significant setbacks in clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products, and may never become profitable.

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

PART I - FINANCIAL INFORMATION

ITEM 1. **FINANCIAL STATEMENTS**

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

	September 30, 2013 (Unaudited)	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 21,177	$ 26,892
Inventory	117	195
Prepaid expenses and other current assets	418	719
Total Current Assets	21,712	27,806
Property and equipment, net	1,417	1,737
Restricted cash	400	400
Other assets	102	–
Total Assets	$ 23,631	$ 29,943
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,489	$ 1,166
Accrued expenses	5,071	4,159
Common stock warrant liability	4,678	6,305
Equipment loans and capitalized leases, current portion	72	69
Total Current Liabilities	11,310	11,699
Long-term debt, net of discount of $3,674 at September 30, 2013 and $0 at December 31, 2012	6,326	–
Equipment loans and capitalized leases, non-current portion	89	148
Other liabilities	431	443
Total Liabilities	18,156	12,290
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 150,000,000 shares authorized at September 30, 2013, 100,000,000 shares authorized at December 31, 2012; 54,946,327 and 43,673,636 shares issued, 54,925,435 and 43,652,744 shares outstanding at September 30, 2013 and December 31, 2012, respectively	55	44
Additional paid-in capital	476,695	455,398
Accumulated deficit	(468,221)	(434,735)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total Stockholders' Equity	5,475	17,653
Total Liabilities & Stockholders' Equity	$ 23,631	$ 29,943

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,	
	2013	2012	2013	2012
Grant revenue	$ 60	$ –	$ 315	$ –
Expenses:				
Research and development	6,574	5,743	21,909	15,482
Selling, general and administrative	4,299	4,255	12,648	9,912
Total expenses	10,873	9,998	34,557	25,394
Operating loss	(10,813)	(9,998)	(34,242)	(25,394)
Change in fair value of common stock warrant liability	(1,059)	(3,309)	1,627	(5,063)
Interest income	1	1	2	5
Interest expense	(353)	(4)	(873)	(12)
Other expense	-	(36)	-	(36)
Net loss	$ (12,224)	$ (13,346)	$ (33,486)	$ (30,500)
Net loss per common share –				
Basic	$ (0.22)	$ (0.31)	$ (0.68)	$ (0.80)
Diluted	$ (0.22)	$ (0.31)	$ (0.69)	$ (0.80)
Weighted average number of common shares outstanding				
Basic	54,792	43,444	49,235	38,061
Diluted	54,792	43,444	50,377	38,061

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

(in thousands)

	Nine Months Ended September 30, 2013	2012
Cash flows from operating activities:		
Net loss	$ (33,486)	$ (30,500)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	537	855
Stock-based compensation and 401(k) match	2,367	1,805
Fair value adjustment of common stock warrants	(1,627)	5,063
Loss on sale or disposal of equipment	–	36
Amortization of discount on long-term debt	302	–
Changes in:		
Inventory	78	(128)
Prepaid expenses and other current assets	301	(723)
Accounts payable	323	(903)
Accrued expenses	912	693
Other assets	(115)	–
Other liabilities	(12)	(19)
Net cash used in operating activities	(30,420)	(23,821)
Cash flows from investing activities:		
Purchase of property and equipment	(204)	(593)
Net cash used in investing activities	(204)	(593)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	15,114	43,605
Proceeds from issuance of long-term debt, net of expenses	9,850	–
Proceeds from exercise of common stock warrants and options	1	6,741
Repayment of equipment loans and capital lease obligations	(56)	(57)
Net cash provided by financing activities	24,909	50,289
Net (decrease) / increase in cash and cash equivalents	(5,715)	25,875
Cash and cash equivalents – beginning of period	26,892	10,189
Cash and cash equivalents – end of period	$ 21,177	$ 36,064
Supplementary disclosure of cash flows information:		
Interest paid	$ 559	$ 10

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 potentially to enable the efficient delivery of our aerosolized KL_4 surfactant, and potentially other aerosolized drugs and inhaled therapies. We believe that our proprietary technologies 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.

Our near-term focus is to develop our KL_4 surfactant and drug delivery technologies to improve 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, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Currently, premature infants with RDS 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 complications. To avoid such adverse results, neonatologists generally provide surfactants as initial therapy only to premature infants with severe RDS where the potential benefits of surfactant therapy outweigh the risks associated with endotracheal intubation and mechanical ventilation. For infants with less severe RDS, neonatologists first attempt to provide respiratory support using a less invasive means, such as nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of these infants do not respond adequately to nCPAP, an outcome referred to as nCPAP failure, and require subsequent surfactant administration via intubation and mechanical ventilation. Since it is not possible to ascertain which patients will experience nCPAP failure, neonatologists treating less severe RDS are faced with a dilemma, because the outcome for those infants who experience nCPAP failure and receive delayed surfactant therapy may not be as favorable as the outcome for those infants who receive surfactant therapy as initial therapy.

With mortality and morbidity rates that have not meaningfully improved over the last decade, we believe that the RDS market is presently underserved. We also believe that our RDS programs, including SURFAXIN® and, if approved, AEROSURF®, have the potential to greatly improve the management of RDS and, over time, become a new standard of care for premature infants with RDS. Moreover, we believe that the neonatal community is increasingly recognizing the potential benefits of (i) a synthetic, peptide-containing surfactant, and more importantly, (ii) a less-invasive method of delivering aerosolized surfactant to treat premature infants at risk of suffering from respiratory disorders.

In 2012, the U.S. Food and Drug Administration (FDA) approved our first KL_4 surfactant drug product, SURFAXIN (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the U.S. On October 4, 2013, we announced that the FDA agreed to updated product specifications that we previously submitted for SURFAXIN. On November 8, 2013, we announced that we have initiated the commercial introduction of SURFAXIN. Our commercial and medical affairs organizations currently are advancing initiatives to communicate that SURFAXIN is available and to secure formulary acceptance from our target hospitals. We are also preparing to support hospitals that order SURFAXIN with in-service training, medical information and other activities intended to promote and enable a deliberate and orderly introduction of SURFAXIN to the neonatal community.

AEROSURF is an investigational combination drug-device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). We are developing AEROSURF to deliver our KL_4 surfactant in aerosolized form to premature infants with RDS. AEROSURF potentially will provide neonatologists with the ability to avoid the invasive procedures currently required to administer surfactant therapy and deliver our KL_4 surfactant in aerosolized form to premature infants supported with nCPAP. For this reason, we believe that AEROSURF, if approved, may enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

On October 17, 2013, we announced that we have submitted an Investigational New Drug (IND) Application to the FDA for our initial AEROSURF phase 2 clinical trial. The FDA has completed its review and cleared our IND and we expect to initiate our phase 2 clinical program in the fourth quarter of 2013.

We are developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant, which is stored as a powder and resuspended to liquid form prior to use, and is being developed with the objective of improving ease of use for healthcare practitioners, as well as potentially prolonging shelf life and eliminating the need for cold-chain storage. We are planning initially to use lyophilized KL4 surfactant in our AEROSURF development program. We are also assessing a potential development plan intended to gain regulatory approval for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially in other markets.

With the assistance of Battelle Memorial Institute (Battelle), we have completed development of a clinic-ready CAG device, which has passed a rigorous design verification testing program, and have manufactured a sufficient number of clinic-ready CAGs to support the initial phase of our AEROSURF phase 2 clinical program. We plan to continue development of our CAG and expect to manufacture additional devices to support completion of our phase 2 clinical program and potentially our phase 3 clinical program. The CAG has been designed to produce aerosolized KL4 surfactant in volumes up to 10 times the output produced by currently available aerosol devices.

AFECTAIR® aerosol-conducting airway connector is our novel disposable device intended to simplify the delivery of our aerosolized KL4 surfactant, and other aerosolized medications and inhaled therapies, to infants in NICUs and pediatric intensive care units (PICUs) who require ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. To gain information and assess the use of this device in different clinical settings, we are continuing a national user experience program at a number of institutions, including leading neonatal thought centers, across the U.S.

We have established our own specialty commercial and medical affairs organizations to focus on neonatal/pediatric respiratory critical care in hospitals across the U.S. These organizations are primarily responsible for the commercial introduction of SURFAXIN and the AFECTAIR device. In the future, we expect that these teams will be able to leverage the experience and relationships gained from the introduction of SURFAXIN to support the potential introductions of our own future pipeline products, beginning with, if approved, AEROSURF and potentially SURFAXIN LS. In addition, we will consider opportunities to leverage our experience and relationships to market and support other synergistic products that could be of benefit in the NICU/PICU.

Our objectives for 2013 include initiating the commercial introduction of SURFAXIN and advancing the AEROSURF phase 2 clinical program. In the future, we expect that we will be able to apply the knowledge and experience gained from these activities to develop a pipeline of innovative products based on our technologies and intended to address other critical care respiratory conditions in the NICU, PICU and intensive care units (ICUs).

An important priority for us is to secure strategic and financial resources to advance our KL4 surfactant and aerosol device development programs and the commercial introduction of our approved RDS products in markets outside the U.S. *See*, Note 2, “Liquidity Risks and Management’s Plans.” While we currently intend to retain all rights and commercialize our approved products in the U.S., we are focused on identifying potential strategic alliances to assist us with our development programs in markets outside the U.S. We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our activities, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. We are focused on securing a significant strategic alliance predominantly to support our activities in the European Union (EU). To date, the primary focus of our discussions has been on AEROSURF. In the future, we may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS, in countries where regulatory approval is facilitated by the information contained in our SURFAXIN new drug application (NDA) approved by the FDA.

There can be no assurance that we will be successful in securing the necessary capital, or concluding any strategic alliance, collaboration arrangement or other similar transaction. *See*, Note 2, “Liquidity Risks and Management’s Plans.”

Note 2 – Liquidity Risks and Management’s Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing and potential commercialization 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 equity programs, and capital equipment financings.

As of September 30, 2013, we had cash and cash equivalents of $21.2 million, approximately $6.6 million of accounts payable and accrued expenses, and $10 million of long-term debt under our Deerfield Facility with Deerfield Management Company, L.P. (Deerfield).

On October 15, 2013, we completed an offering under our At-the-Market Program (ATM Program) (*see*, Note 4, "Stockholders' Equity – Common Stock Offerings – At-the-Market Program") with Stifel, Nicolaus & Company, Incorporated (Stifel) and issued 713,920 shares of our common stock resulting in net proceeds to us (after deducting commissions due to Stifel) of approximately $1.9 million. Through our ATM Program, subject to market conditions, we have the ability to sell up to approximately $23 million of common stock at such times and in such amounts that we deem appropriate. However, use of the ATM Program is subject to market and other conditions and the ATM Program can be cancelled at any time by either party. There can be no assurance that the ATM Program will be available when needed, if at all.

On November 5, 2013, we completed a public offering of 25 million shares of common stock, at a price of $2.00 per share resulting in gross proceeds of $50.0 million ($46.8 million net after commissions, discounts and expenses). In addition, we also granted the underwriters a 30-day option to purchase up to an additional 3.75 million shares of common stock (over-allotment) at an offering price of $2.00 per share. On November 8, 2013, we received notification that the underwriters have exercised the full over-allotment and will purchase an additional 3.75 million shares. This transaction is expected to close on or about November 14, 2013 and result in additional net proceeds to us of approximately $7.1 million.

We also have met the conditions for, and expect in early December to receive, an additional advance of $20 million under the Deerfield Facility, which became due upon the first commercial sale of SURFAXIN drug product. *See*, Note 6, "Long-Term Debt – Loan Facility with Deerfield."

Before any additional financings, including under our ATM Program and taking into account the additional approximately $7.1 million expected from the underwriters' exercise of the over-allotment in our November public offering and the expected $20 million advance under the Deerfield Facility, we anticipate that we will have sufficient cash available to support our operations and debt service obligations through 2015.

Our future capital requirements depend upon many factors, primarily the success of our efforts to (i) execute the commercial introduction of SURFAXIN and AFECTAIR in the U.S., as planned; (ii) advance the AEROSURF development program to completion of the phase 2 clinical program in mid-2015; and (iii) secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, the commercial introduction of SURFAXIN, AEROSURF, AFECTAIR and potentially SURFAXIN LS, in markets outside the U.S. We believe that, if we are successful with the commercial introduction of SURFAXIN and if we are able to complete the AEROSURF phase 2 clinical program on a timely basis and obtain encouraging results, our ability to enter into a significant strategic alliance will be enhanced. There can be no assurance, however, that our efforts will be successful, or that we will be able to obtain additional capital to support our activities when needed on acceptable terms, if at all.

Even if we succeed with the commercial introduction of SURFAXIN and the AFECTAIR device as planned, given the time required to secure formulary acceptance of SURFAXIN at our target hospitals, we expect our revenues from SURFAXIN and AFECTAIR to be modest in the first 12-18 months and then increase over time as our products gain hospital acceptance. As a result, our cash outflows for operations, debt service and development programs are expected to outpace the rate at which we may generate revenues for several years. To execute our business strategy and fund our operations over the long term, we will require significant additional infusions of capital until such time as the net revenues from SURFAXIN, AFECTAIR and, if approved, AEROSURF, from potential strategic alliances and from other sources are sufficient to offset our cash flow requirements. To secure the necessary capital, we would prefer to enter into strategic alliances or collaboration agreements with partners that could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) and introduce our approved products in various markets outside the U.S. We also plan to consider other public and private equity offerings, including under our ATM Program, as well as other financing transactions, such as secured equipment financing facilities or other similar transactions.

As of September 30, 2013, we had outstanding warrants to purchase approximately 10.3 million shares of our common stock at various prices, exercisable on different dates through 2019. Of these warrants, approximately 2.3 million warrants were issued to Deerfield in connection with the first advance under the Deerfield Facility. Upon receipt of the final $20 million advance under the Deerfield Facility, which is anticipated on or about December 3, 2013, we will issue warrants to purchase an additional 4.66 million shares of our common stock at an exercise price of $2.81 per share (we refer to these warrants and the warrants previously issued to Deerfield as the 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 to purchase approximately 4.9 million shares of common stock that were issued in February 2011, are exercisable for five-years, and contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. These warrants were originally issued with an exercise price of $3.20 per share and thereafter adjusted downward, first to $2.80 per share following a public offering in March 2012 and then to $1.50 per share following a public offering in May 2013. Although we believe that, in the future, we will secure additional capital from the exercise of at least a portion of our outstanding warrants, there can be no assurance that the market price of our common stock will equal or exceed price levels that make exercise of outstanding warrants likely, or, even if the price levels are sufficient, that holders of our warrants will choose to exercise any or all of their warrants prior to the warrant expiration date. 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, 2013, 150 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, and approximately 71.7 million shares of common stock were available for issuance and not otherwise reserved. As of November 8, 2013, following the financings under our ATM Program, our public offering, and establishment of additional reserves for the shares expected to be issued in connection with the underwriters' exercise of the over-allotment in our November public offering and with respect to the warrants expected to be issued to Deerfield upon receipt of the $20 million advance in early December, approximately 42 million shares of common stock were available for issuance and not otherwise reserved.

Although we currently believe that we will be able to execute our business plan and accomplish our objectives, there can be no assurance that we will be successful. There can be no assurance that we will be successful in securing the needed capital, through strategic alliances, collaboration arrangements, financings, debt arrangements and other transactions. Failure to secure the necessary additional capital would have a material adverse effect on our business, financial condition and results of operations.

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial information in accordance with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete 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, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. There have been no changes to our critical accounting policies since December 31, 2012. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2012 that we filed with the Securities and Exchange Commission (SEC) on March 15, 2013 (2012 Form 10-K). Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

Inventory

Inventories are determined at the lower of cost or market value with cost determined under the specific identification method. We assess the potential capitalization of inventory and the timing of when the related costs are expected to be recoverable through the commercialization of our products. Costs incurred prior to FDA approval of SURFAXIN drug product and registration of our initial AFECTAIR device have been recorded in our statement of operations as research and development expense. Due to a delay in commercial availability of SURFAXIN drug product, previously capitalized raw material costs of $195,072 were charged to research and development expense in the first quarter of 2013, as these raw materials were no longer expected to be used for commercial production.

Inventory as of September 30, 2013 consists of AFECTAIR devices available for commercial sale. Inventory costs for our AFECTAIR device consist primarily of third-party manufacturing fees, freight, and indirect personnel overhead costs.

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. For the nine months ended September 30, 2012, research and development expense includes a $0.5 million charge related to a milestone payment that became payable to Johnson & Johnson (J&J) upon FDA approval of SURFAXIN, in accordance with terms of our license agreement with J&J.

Net loss per common share

Basic net loss per common 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.

In accordance with Accounting Standards Codification (ASC) Topic 260, "*Earnings per Share*," when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of certain warrants classified as derivative liabilities results in an adjustment to the net loss; and the dilutive impact of the assumed exercise of the warrants results in an adjustment to the weighted average common shares outstanding. We utilize the treasury stock method to calculate the dilutive impact of the assumed exercise of the warrants. For the nine months ended September 30, 2013, the effect of the adjustments for warrants issued in February 2011 was dilutive. For the three months ended September 30, 2013 and for the three and nine months ended September 30, 2012, the effect of the adjustments for all warrants classified as derivative liabilities was non-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,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
Numerator:				
Net loss as reported	$ (12,224)	$ (13,346)	$ (33,486)	$ (30,500)
Less: income from change in fair value of warrant liability	–	–	(1,525)	–
Numerator for diluted net loss per common share	$ (12,224)	$ (13,346)	$ (35,011)	$ (30,500)
Denominator:				
Basic weighted average common shares outstanding	54,792	43,444	49,235	38,061
Dilutive common shares from assumed warrant exercises	–	–	1,142	–
Diluted weighted average common shares outstanding	54,792	43,444	50,377	38,061

As of September 30, 2013 and 2012, 10.7 million and 12.0 million shares of common stock potentially issuable upon the exercise of certain stock options and warrants were excluded from the computation of diluted net loss per common share because their impact would have been anti-dilutive.

Recent accounting pronouncements

There were no new accounting pronouncements issued during the nine months ended September 30, 2013 that are expected to have a material impact on the Company's financial position, operating results, cash flows or disclosures.

Note 4 – Stockholders' Equity

Registered Public Offerings

On May 15, 2013, we completed a registered public offering of 9.5 million shares of our common stock, at a price of $1.50 per share resulting in gross proceeds of $14.3 million ($13.2 million net). We also granted the underwriter a 30-day option to purchase up to an additional 1.425 million shares of common stock at an offering price of $1.50 per share. On May 31, 2013, the underwriter exercised its option and purchased 1.347 million additional shares of common stock for net proceeds to us (after underwriter fees) of $1.9 million. In connection with this offering, we agreed not to issue or sell (with certain limited exceptions) securities for a period of 90 days after the date of the prospectus supplement ending August 8, 2013. Regarding our ATM Program, we agreed not to issue or sell securities for a period of 30 days after the date of the underwriting agreement ending on June 9, 2013.

At-the-Market Program

In February 2013, we entered into an At-the-Market Equity Offering Sales Agreement with 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. 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*, Note 17, "Subsequent Events – ATM Program," to the consolidated financial statements in our 2012 Form 10-K.

Committed Equity Financing Facility (CEFF)

We had a CEFF dated June 11, 2010 with Kingsbridge Capital Limited (Kingsbridge), under which, for a period of up to three years, Kingsbridge was committed to purchase, subject to certain conditions, newly issued shares of our common stock. Our ability to access the CEFF was subject to certain covenants and conditions, including stock price and volume limitations. For a detailed description of our CEFF, *see*, Note 10, "Stockholders' Equity – Registered Public Offerings – Committed Equity Financing Facility (CEFF)," to the consolidated financial statements in our 2012 Form 10-K.

The CEFF expired on June 11, 2013 with approximately 1.1 million available shares not issued.

Note 5 – Fair Value of Financial Instruments

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

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

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

Fair Value on a Recurring Basis

The table below categorizes assets and liabilities measured at fair value on a recurring basis as of September 30, 2013 and December 31, 2012:

	Fair Value September 30, 2013	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Money Market	$ 19,877	$ 19,877	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 20,277	$ 20,277	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 4,678	$ –	$ –	$ 4,678

	Fair Value December 31, 2012	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Money Market	$ 23,377	$ 23,377	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 23,777	$ 23,777	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 6,305	$ –	$ –	$ 6,305

The tables below summarizes the activity of Level 3 inputs measured on a recurring basis for the nine months ended September 30, 2013 and 2012:

(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

(in thousands)	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2011	$ 6,996
Exercise of warrants	(136)
Change in fair value of common stock warrant liability	5,063
Balance at September 30, 2012	$ 11,923

The significant unobservable inputs used in the fair value measurement of common stock warrants 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, the fair value measurement of certain five-year warrants issued in February 2011 also takes 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, would result in significantly higher or lower fair value measurements.

Significant Unobservable Input Assumptions of Level 3 Valuations	September 30, 2013	December 31, 2012
Historical Volatility	55% - 61%	56% -80%
Expected Term (in years)	0.6 – 2.4	1.4 – 3.2
Risk-free interest rate	0.05% - 0.45%	0.16% - 0.36%

Fair Value of Long-Term Debt

As of September 30, 2013, the carrying value of our long-term debt, net of discounts, approximates fair value. We had no long-term debt as of December 31, 2012. We estimate the fair value of the Deerfield Facility using a discounted cash flow analysis. This analysis utilizes certain Level 3 unobservable inputs, including the effective interest rate and current cost of capital. Considerable judgment is required to interpret market data and to develop estimates of fair value. The estimates presented are not necessarily indicative of amounts we could realize in a current market exchange. The use of alternative market assumptions and estimation methodologies could have a material effect on these estimates of fair value.

Note 6 – Long-term Debt

Loan Facility with Deerfield

On February 13, 2013, we entered into a secured loan facility (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield) for up to $30 million in secured financing in 2013. Deerfield advanced to us $10 million upon execution of the agreement and agreed to advance an additional $20 million, subject to certain conditions, on or about the date of the first commercial sale of SURFAXIN drug product (Milestone Date), if the Milestone Date occurs on or before December 31, 2013. On November 8, 2013, we notified Deerfield that the first commercial sale of SURFAXIN has occurred, and anticipate receipt of the $20 million advance on or about December 3, 2013.

The loan may be prepaid in whole or in part without penalty at any time. In addition, the principal amount of the loan may be reduced to the extent that holders of the notes elect to apply all or a portion of the principal amount outstanding under the loan to satisfy the exercise price of all or a portion of the Deerfield Warrants upon exercise. The principal amount of the loan is payable in equal annual installments on the fourth, fifth and sixth anniversaries of the Deerfield Facility agreement, provided that the amount payable on the fourth anniversary shall be deferred for one year if either (i) our “Net Sales” (defined below) for the immediately preceding 12-month period are at least $20 million, or (ii) our “Equity Value” (defined below) 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) our “Net Sales” for the immediately preceding 12 month period are at least $30 million, or (ii) our “Equity Value” is at least $250 million. For the purposes of the foregoing deferrals of principal, “Net Sales” means, without duplication, the gross amount invoiced by us or on our behalf, any of our subsidiaries or any direct or indirect assignee or licensee for products, sold globally in bona fide, arm’s length transactions, less customary deductions determined without duplication in accordance with generally accepted accounting principles; and “Equity Value” means, with respect to each measurement date, the product of (x) the number of issued and outstanding shares of our common stock on such measurement date multiplied by (y) the per share closing price of our common stock on such measurement date. Accordingly, if the milestones are achieved in each year, payment of the principal amount could be deferred until the sixth anniversary date of the loan on February 13, 2019.

Any amounts received and outstanding under the Deerfield Facility will accrue interest at a rate of 8.75%, payable quarterly in cash. The Deerfield Facility agreement contains customary terms and conditions but does not require us to meet minimum financial and revenue performance covenants. In connection with each advance, Deerfield has received and, upon advance of the additional $20 million, will receive, a transaction fee equal to 1.5% of the amount disbursed. The facility agreement also contains various representations and warranties and affirmative and negative covenants customary for financings of this type, including restrictions on our ability to incur additional indebtedness and grant additional liens on our assets. In addition, all amounts outstanding under the Deerfield Facility may become immediately due and payable upon (i) an “Event of Default,” as defined in the Deerfield Facility agreement, in which case Deerfield would have the right to require us to repay the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the occurrence of certain events as defined in the facility agreement, including, among other things, the consummation of a change of control transaction or the sale of more than 50% of our assets (a Major Transaction).

In connection with the execution of the Deerfield Facility and receipt of the initial disbursement of $10 million, we issued to Deerfield warrants to purchase approximately 2.3 million shares of our common stock at an exercise price of $2.81. Upon disbursement of the additional $20 million loan under the facility agreement, we will issue additional warrants to Deerfield to purchase an additional 4.66 million shares of our common stock at an exercise price of $2.81 per share of common stock. The number of shares of common stock into which the Deerfield Warrants are exercisable and the exercise price of any Deerfield Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock.

The Deerfield Warrants will expire on the sixth anniversary of the facility agreement and contain certain limitations that generally prevent the holder from acquiring shares upon exercise of a Deerfield Warrant that would result in the number of shares beneficially owned by it to exceed 9.985% of the total number of shares of common stock then issued and outstanding. The holder of a Deerfield Warrant may exercise all or a portion of such Deerfield Warrant either for cash or on a cashless basis. In connection with a Major Transaction, as defined in the Deerfield Warrants, to the extent of consideration payable to stockholders in cash in connection with such Major Transaction, the holder may have the option to redeem the Deerfield Warrant or that portion of the Deerfield Warrant for cash in an amount equal to the Black-Scholes value (as defined in the Deerfield Warrant) of the Deerfield Warrant or that portion of the Deerfield Warrant redeemed. In addition, in connection with a Major Transaction, to the extent of any consideration payable to stockholders in securities, or in the event of an Event of Default, the holder may have the option to exercise the Deerfield Warrant and receive therefor that number of shares of Common Stock that equals the Black-Scholes value of the Deerfield Warrant or that portion of the Deerfield Warrant exercised. Prior to the holder exercising the Deerfield Warrant for shares in such transactions, the Company may elect to terminate the Deerfield Warrant or that portion of the Deerfield Warrant and pay the holder cash in an amount equal to the Black-Scholes value of the Deerfield Warrant.

We have recorded the loan as long-term debt at its face value of $10.0 million less debt discounts and issuance costs consisting of (i) $3.8 million fair value of the Deerfield Warrants issued upon the advance of the $10 million initial disbursement, and (ii) a $150,000 transaction fee. The discount is being accreted to the $10 million loan over its term using the effective interest method. The Deerfield Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815 *"Derivatives and Hedging – Contracts in Entity's Own Equity"* (ASC 815) and have been classified as equity.

The fair value of the Deerfield Warrants at issuance was calculated using the Black-Scholes option-pricing model. The significant Level 3 unobservable inputs used in valuing the Deerfield Warrants are the historical volatility of our common stock market price, expected term of the warrants, and the risk-free interest rate based on the U.S. Treasury yield curve in effect at the measurement date. Any significant increases or decreases in the unobservable inputs, with the exception of the risk-free interest rate, would have resulted in a significantly higher or lower fair value measurement.

Significant Unobservable Input Assumptions of Level 3 Valuations	
Historical Volatility	101%
Expected Term (in years)	6.0
Risk-free interest rate	1.175%

Long-term debt as of September 30, 2013 consists solely of amounts due under the Deerfield Facility as follows:

Note Payable	$ 10,000
Unamortized discount	(3,674)
Long-term debt, net of discount	$ 6,326

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

(in thousands)	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
	2013	**2012**	**2013**	**2012**
Cash interest expense	$ 221	$ –	$ 551	$ –
Non-cash amortization of debt discounts	125	–	302	–
Amortization of debt costs	5	–	13	–
Total Deerfield Facility interest expenses	$ 351	$ –	$ 866	$ –

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

Note 7 – Common Stock Warrant Liability

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC 815, either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement.

The registered warrants that we issued in May 2009 and February 2010 have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using the Black-Scholes option-pricing model. The February 2011 five-year warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model. *See*, Note 8, "Common Stock Warrant Liability," to the consolidated financial statements in our 2012 Form 10-K for a discussion of common stock warrant liability.

Selected terms and estimated fair value of warrants accounted for as derivative liabilities at September 30, 2013 are as follows:

Issuance Date	Number of Warrant Shares	Exercise Price	Warrant Expiration Date	Fair Value of Warrants *(in thousands)*	
				Issuance Date	September 30, 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	2
2/22/2011	4,948,750	1.50	2/22/2016	8,004	4,676

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 8 – Stock Options and Stock-Based Employee Compensation

We recognize in our 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 that uses weighted-average assumptions noted in the following table:

	2013	2012
Weighted-average expected volatility	110%	110%
Weighted-average expected term (in years)	4.7	4.8
Weighted-average risk-free interest rate	0.74%	0.79%
Expected dividends	–	–

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research & Development	$ 210	$ 150	$ 551	$ 388
Selling, General & Administrative	431	324	1,053	889
Total	$ 641	$ 474	$ 1,604	$ 1,277

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, 2012 that we filed with the Securities and Exchange Commission (SEC) on March 15, 2013 (2012 Form 10-K) and our other filings with the SEC, and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.

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

OVERVIEW

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

Our near-term focus is to develop our KL_4 surfactant and drug delivery technologies to improve 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, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Currently, premature infants with RDS 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 complications. To avoid such adverse results, neonatologists generally provide surfactants as initial therapy only to premature infants with severe RDS where the potential benefits of surfactant therapy outweigh the risks associated with endotracheal intubation and mechanical ventilation. For infants with less severe RDS, neonatologists first attempt to provide respiratory support using a less invasive means, such as nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of these infants do not respond adequately to nCPAP, an outcome referred to as nCPAP failure, and require subsequent surfactant administration via intubation and mechanical ventilation. Since it is not possible to ascertain which patients will experience nCPAP failure, neonatologists treating less severe RDS are faced with a dilemma, because the outcome for those infants who experience nCPAP failure and receive delayed surfactant therapy may not be as favorable as the outcome for those infants who receive surfactant therapy as initial therapy.

With mortality and morbidity rates that have not meaningfully improved over the last decade, we believe that the RDS market is presently underserved. We also believe that our RDS programs, including SURFAXIN® and, if approved, AEROSURF®, have the potential to greatly improve the management of RDS and, over time, become a new standard of care for premature infants with RDS. Moreover, we believe that the neonatal community is increasingly recognizing the potential benefits of (i) a synthetic, peptide-containing surfactant, and more importantly, (ii) a less-invasive method of delivering aerosolized surfactant to treat premature infants at risk of suffering from respiratory disorders.

In 2012, the U.S. Food and Drug Administration (FDA) approved our first KL_4 surfactant drug product, SURFAXIN (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the U.S. On October 4, 2013, we announced that the FDA agreed to updated product specifications that we previously submitted for SURFAXIN. On November 8, 2013, we announced that we have initiated the commercial introduction of SURFAXIN. Our commercial and medical affairs organizations currently are advancing initiatives to communicate that SURFAXIN is available and to secure formulary acceptance from our target hospitals. We are also preparing to support hospitals that order SURFAXIN with in-service training, medical information and other activities intended to promote and enable a deliberate and orderly introduction of SURFAXIN to the neonatal community.

AEROSURF is an investigational combination drug-device product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG). We are developing AEROSURF to deliver our KL4 surfactant in aerosolized form to premature infants with RDS. AEROSURF potentially will provide neonatologists with the ability to avoid the invasive procedures currently required to administer surfactant therapy and deliver our KL4 surfactant in aerosolized form to premature infants supported with nCPAP. For this reason, we believe that AEROSURF, if approved, may 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 developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant, which is stored as a powder and resuspended to liquid form prior to use, and is being developed with the objective of improving ease of use for healthcare practitioners, as well as potentially prolonging shelf life and eliminating the need for cold-chain storage. We are planning initially to use lyophilized KL4 surfactant in our AEROSURF development program. We are also assessing a potential development plan intended to gain regulatory approval for SURFAXIN LS™, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially in other markets.

AFECTAIR® aerosol-conducting airway connector is our novel disposable device intended to simplify the delivery of our aerosolized KL4 surfactant, and other aerosolized medications and inhaled therapies, to infants in NICUs and pediatric intensive care units (PICUs) who require ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. To gain information and assess the use of this device in different clinical settings, we are continuing a national user experience program at a number of institutions, including leading neonatal thought centers, across the U.S.

We have established our own specialty commercial and medical affairs organizations to focus on neonatal/pediatric respiratory critical care in hospitals across the U.S. These organizations are primarily responsible for the commercial introduction of SURFAXIN and the AFECTAIR device. In the future, we expect that these teams will be able to leverage the experience and relationships gained from the introduction of SURFAXIN to support the potential introductions of our own future pipeline products, beginning with, if approved, AEROSURF and potentially SURFAXIN LS. In addition, we will consider opportunities to leverage our experience and relationships to market and support other synergistic products that could be of benefit in the NICU/PICU.

Our objectives for 2013 include initiating the commercial introduction of SURFAXIN and advancing the AEROSURF phase 2 clinical program. In the future, we expect that we will be able to apply the knowledge and experience gained from these activities to develop a pipeline of innovative products based on our technologies and intended to address other critical care respiratory conditions in the NICU, PICU and intensive care units (ICUs).

An important priority for us is to secure strategic and financial resources to advance our KL4 surfactant and aerosol device development programs and the commercial introduction of our approved RDS products in markets outside the U.S. *See*, "– Liquidity and Capital Resources – Overview." While we currently intend to retain all rights and commercialize our approved products in the U.S., we are focused on identifying potential strategic alliances to assist us with our development programs in markets outside the U.S. We seek strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our activities, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. We are focused on securing a significant strategic alliance predominantly to support our activities in the European Union (EU). To date, the primary focus of our discussions has been on AEROSURF. In the future, we may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS, in countries where regulatory approval is facilitated by the information contained in our SURFAXIN new drug application (NDA) approved by the FDA.

There can be no assurance that we will be successful in securing the necessary capital, or concluding any strategic alliance, collaboration arrangement or other similar transaction. *See*, "– Liquidity and Capital Resources."

Business and Pipeline Programs Update

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business," in our 2012 Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and our current and planned KL4 pipeline programs.

Following are updates to our pipeline programs since the filing of our 2012 Form 10-K:

- SURFAXIN for the Prevention of Respiratory Distress Syndrome (RDS) in Premature Infants at High Risk for RDS

  In April 2013, we received a response from the FDA to a submission we made in the fourth quarter of 2012 concerning our improved analytical chemistry method and updated product specifications for SURFAXIN drug product. The April FDA correspondence included a request for specific information and documents, recommendations regarding documentation of product specifications generally and for the upper limit of a single product specification, and a request for supporting data using the improved and revalidated analytical chemistry method. We completed the required work and submitted our response to the FDA on June 7, 2013. On October 4, 2013, we received confirmation that the FDA has agreed with our updated product specifications. We have now manufactured new drug product and have initiated the commercial introduction of SURFAXIN.

  On August 7, 2013, we entered into a Pharmaceutical Manufacturing and Supply Agreement with our contract manufacturer, DSM Pharmaceuticals, Inc. (DSM) providing for the manufacture of SURFAXIN drug product. We anticipate that DSM will become our principal manufacturer of SURFAXIN upon expiration of the lease for our manufacturing operations in Totowa, NJ, currently in mid-2015. *See*, "– Results of Operations – Research and Development Expenses – Product Development and Manufacturing."

- AEROSURF

  On October 17, 2013, we announced that we have submitted an Investigational New Drug (IND) Application to the FDA for our AEROSURF phase 2 clinical program. The FDA has completed its review and cleared our IND, and we expect to initiate our phase 2 clinical program in the fourth quarter of 2013.

  The primary goal of the study (phase 2a) of the AEROSURF clinical program is to evaluate the safety and tolerability of a single exposure of aerosolized KL4 surfactant drug product. This study is planned as an escalating dose study evaluating three dose levels of aerosolized KL4 surfactant. The comparator is nCPAP alone. The study will be conducted in three centers in the U.S. and is expected to be completed by mid-2014. The design of the second study (phase 2b) will be informed by the results of the phase 2a study. The primary objective of this study will be to determine the optimal dose and to estimate the efficacy margin, information that will inform the design of the phase 3 efficacy and safety study. Phase 2b is expected to be conducted in multiple centers and completed by mid-2015.

  DSM has manufactured the clinical lyophilized KL4 surfactant drug product needed to conduct the phase 2a study of our AEROSURF clinical program. On October 24, 2013, we entered into a Master Services Agreement with DSM providing for the further development of our lyophilized KL4 surfactant and manufacture of additional drug supply needed to complete our phase 2 clinical program, and potentially for our phase 3 clinical program and, if approved, commercial supply.

  With the assistance of Battelle Memorial Institute (Battelle), we have completed development of a clinic-ready CAG device, which has passed a rigorous design verification testing program, and have manufactured a sufficient number of clinic-ready CAGs to support the initial phase of our AEROSURF clinical program. We plan to continue development of our CAG and expect to manufacture additional devices to support completion of our phase 2 clinical program and potentially our phase 3 clinical program. The CAG has been designed to produce aerosolized KL4 surfactant in volumes up to 10 times the output produced by currently available aerosol devices.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2012. For more information on critical accounting policies, *see*, Note 3, "Summary of Significant Accounting Policies and Recent Accounting Pronouncements," to the consolidated financial statements included in our 2012 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the three months ended September 30, 2013 and 2012 was $12.2 million (or $0.22 basic net loss per share) and $13.3 million (or $0.31 basic net loss per share), respectively. Included in the net loss is the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash expense of $1.1 million and $3.3 million for 2013 and 2012, respectively.

The net loss for the nine months ended September 30, 2013 and 2012 was $33.5 million (or $0.68 basic net loss per share) and $30.5 million (or $0.80 basic net loss per share), respectively. Included in the net loss is the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $1.6 million and non-cash expense of $5.1 million in 2013 and 2012, respectively.

The operating loss for the three months ended September 30, 2013 and 2012 was $10.8 million and $10.0 million, respectively. The increase in operating loss from 2012 to 2013 is primarily due to a $0.6 million increase in investment in the AEROSURF development program, primarily to develop and manufacture our CAG devices for clinical use in the AEROSURF phase 2a clinical study and further development of our lyophilized KL_4 surfactant manufacturing process at DSM.

The operating loss for the nine months ended September 30, 2013 and 2012 was $34.2 million and $25.4 million, respectively. The increase in operating loss from 2012 to 2013 is primarily due to (i) a $3.3 million increase in investment in our own specialty commercial and medical affairs organizations that are focused on neonatal/pediatric respiratory critical care in NICUs/PICUs across the U.S., (ii) a $4.0 million increase in investment in the AEROSURF development program, primarily to develop and manufacture our CAG for clinical use in our AEROSURF phase 2 clinical studies, and completion of the technology transfer and further development of our lyophilized KL_4 surfactant manufacturing process at DSM, and (iii) a $1.5 million increase in purchases of raw materials to manufacture drug product for SURFAXIN and our AEROSURF development program.

Grant Revenue

For the three and nine months ended September 30, 2013, we recognized $0.1 million and $0.3 million, respectively, of grant revenue. The grant revenue represents funds received and expended under a Small Business Innovation Research (SBIR) Phase I award from National Institute of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) Center for Medical Counter Measures Against Radiation and Nuclear Threats to assess the ability of KL_4 surfactant to mitigate the effects of acute radiation exposure to the lung, including acute pneumonitis and delayed lung injury. The total amount of the award is $0.6 million and funds received and expended from inception of the award through September 30, 2013 have totaled $0.5 million. The remainder of the award is expected to be received and expended in 2013. We did not recognize any grant revenues for the comparable periods in 2012.

We believe that our aerosolized KL_4 surfactant may be an effective intervention for people at risk for, or with, Acute Lung Injury (ALI), and that our development work with AEROSURF for RDS may form the basis for a potential pipeline of products to address ALI. We are collaborating with leading research institutions in a series of preclinical studies funded through various U.S. government-sponsored, biodefense-related initiatives, including NIAID.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we track such costs by category rather than by project. As many of our research and development activities form a foundation for the development of our KL_4 surfactant and drug delivery technologies, they benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist primarily of expenses associated with (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs.

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

(in thousands)	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Product development and manufacturing	$ 4,769	$ 4,258	$ 16,591	$ 11,298
Medical and regulatory operations	1,506	1,400	4,416	3,475
Direct preclinical and clinical programs	299	85	902	709
Total Research & Development Expenses	$ 6,574	$ 5,743	$ 21,909	$ 15,482

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.4 million for each of the three months ended September 30, 2013 and 2012, respectively; and $1.1 million and $1.2 million for the nine months ended September 30, 2013 and 2012, respectively.

Product Development and Manufacturing

Product development and manufacturing includes (i) the cost of our manufacturing operations, both in-house and with our CMO, validation activities and quality assurance and analytical chemistry capabilities to support production of drug supply for our KL4 surfactant products, in conformance with current good manufacturing practices (cGMP); (ii) design and development activities related to our CAG devices for use in our planned AEROSURF phase 2 clinical program; (iii) design and development activities related to our AFECTAIR aerosol-conducting airway connector; and (iv) pharmaceutical 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, 2013 increased $0.5 million as compared to the same period in 2012, primarily due to costs associated with the further development of our KL4 surfactant manufacturing process at DSM.

Product development and manufacturing expenses for the nine months ended September 30, 2013 increased $5.3 million from the comparable period in 2012 primarily due to (i) costs of design and development activities related to our CAG for use in our planned AEROSURF phase 2 clinical trials, including work with third party device experts and work that we began in June 2012 with Battelle, which is assisting with design, testing, and manufacture of clinic-ready CAG devices; (ii) costs associated with the technical transfer and further development of our KL4 surfactant manufacturing processes at DSM; and (iii) purchases of active pharmaceutical ingredients (APIs) used in the production of SURFAXIN and our lyophilized KL4 surfactant, development activities, including preparation of our CAG for use in our anticipated AEROSURF phase 2 clinical program, and to support completion of the technical transfer and further development of our KL4 surfactant manufacturing process at DSM.

We have invested, from the beginning of 2012 through September 2013, approximately $7 million to develop the CAG and complete the technology transfer and further develop our lyophilized KL4 surfactant process at DSM, in preparation for initiation of the AEROSURF clinical program.

We believe that our RDS product portfolio, based on our novel synthetic, peptide-containing KL4 surfactant, has the potential to greatly improve the management of RDS and, over time, may enable the treatment of a significantly greater number of premature infants at risk for RDS who could benefit from surfactant therapy but are currently not treated. We are implementing a long-term manufacturing strategy intended to assure that we have and maintain the capabilities and resources needed to give meaning to this vision.

As we undertake the commercial introduction of SURFAXIN and initiate our phase 2 clinical program for AEROSURF in the fourth quarter of 2013, we are planning for long-term continuity of supply and continued integrity and reliability of our manufacturing and quality assurance processes. We seek to build a foundation to support our anticipated long-term needs, and intend to make appropriate capital investments in the near-term, balance the use of our available resources against our short-term revenue expectations, and maintain flexibility in planning our manufacturing activities and goals.

We have secured an extension of the lease for our manufacturing operations at Totowa, NJ, which was scheduled to expire in December 2014, until to June 30, 2015. We continue to explore possible alternatives that potentially may enable longer-term utilization of that facility. In addition, in 2012, to secure an additional source to manufacture commercial supply of SURFAXIN, we initiated a technology transfer of our SURFAXIN manufacturing process to DSM. We also entered into a supply agreement with DSM that provides for the manufacture of commercial supply of SURFAXIN drug product through December 31, 2015, with such further extensions at that time as may be agreed by the parties. We currently plan to complete the technology transfer to DSM and manufacture process validation batches of SURFAXIN in the fourth quarter of 2013. After time for stability assessment and FDA review, we expect that DSM may be approved for commercial production of SURFAXIN in the fourth quarter of 2014.

For our lyophilized KL4 surfactant, as noted above (*see*, "– Overview – Business and Pipeline Programs Update – AEROSURF," and "– SURFAXIN LS"), we completed the technology transfer of our lyophilized KL4 surfactant manufacturing process to DSM and have manufactured a supply of KL4 surfactant for use in the initial phase of our AEROSURF clinical program. We have entered into a Master Services Agreement for the further development of KL4 surfactant, potentially to complete our AEROSURF phase 2 clinical program, and potentially our AEROSURF phase 3 clinical program, as well as other pipeline programs. For the life cycle management of SURFAXIN, we are assessing a potential development plan that will allow for the conversion of our liquid formulation to a lyophilized dosage form, SURFAXIN LS, and gain regulatory approval in the U.S. and potentially in other markets.

Consistent with our long-term manufacturing strategy, we have initiated a project to identify a potential second CMO to manufacture clinical and commercial supply and assure a continuous and back up supply of our KL4 surfactant drug product. We are in preliminary discussions with several CMOs with a plan to initiate activities in the fourth quarter of 2013. We believe that, by manufacturing our drug product at our Totowa operations and with CMOs, we improve our ability to manage the level of our capital investments, maintain an appropriate balance between our fixed costs and variable expense while maintaining flexibility and reducing the risk profile of meeting the long-term requirements for development and commercial supply of our drug products.

We believe we have executive management and manufacturing capabilities to assure and support our long-term success. Our executive team includes leaders in pharmaceutical and biopharmaceutical drug product manufacturing, with extensive experience in manufacturing both small and large molecules, biological and sterile drug/device combination products in both domestic and overseas operations, and supply chain; as well as in worldwide quality operations to assure consistent and continued quality and cGMP compliance for our products, whether manufactured on our own or with a CMO. Our manufacturing operations are lead by seasoned professionals with broad technical and managerial skills in all facets of our KL4 surfactant manufacturing process, expertise built on many years of accumulated knowledge in biopharmaceutical manufacturing, facility management, process and cleaning validation, sterility assurance and microbiological analyses, clean room operation and direction of formulation and aseptic filling of our drug product. We believe we can leverage the extensive experience that we have gained from having owned our own manufacturing operations since 2005 to flexibly respond over time and provide for the continued manufacture of our KL4 surfactant drug product, on our own or with our CMO.

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 both SURFAXIN and AFECTAIR 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 costs for the nine months ended September 30, 2013 increased $0.9 million compared to the same period in 2012, primarily due to investment in our medical affairs organization to support the commercial introduction of SURFAXIN and the AFECTAIR device for infants.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) development activities, including for the anticipated AEROSURF clinical program, toxicology studies and other preclinical studies to obtain data to support our Investigational New Drug (IND) Application and, potentially, our New Drug Application (NDA) filings for AEROSURF, potentially SURFAXIN LS, and our other product candidates; and (ii) activities, if any, 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 expense for the three and nine months ended September 30, 2013 increased $0.2 million as compared to the same periods in 2012 primarily due to preparatory activities for our planned AEROSURF phase 2 clinical trials. Such preparatory activities include the manufacture of clinic-ready CAG devices, implementation of clinical data management systems and selection of clinical site locations. Costs in 2012 included a $0.5 million charge related to a milestone payment that became payable to Johnson and Johnson (J&J) upon FDA approval of SURFAXIN in March 2012.

We anticipate that direct clinical program costs associated with conducting the AEROSURF phase 2 clinical program will be approximately $8 -10 million through the completion of phase 2b in 2015.

Our drug research and development activities are focused on the management of RDS in premature infants. To prepare for our AEROSURF clinical program, we previously conducted preliminary meetings with the FDA and we have engaged regulatory consultants to assist us in implementing and, as needed, refining our development plan. We also plan to retain regulatory consultants to assist us in engaging with international regulatory authorities regarding the AEROSURF development plan. We filed an IND with the FDA in October 2013. The FDA has completed its review and cleared our IND, and we expect to initiate our phase 2 program in the fourth quarter of 2013. We are also assessing a potential development plan intended to gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, in the U.S. and potentially other major markets. We previously discussed with the FDA potential development activities that may be needed to support regulatory approval of SURFAXIN LS and expect to engage in further discussions with the FDA in this regard. For future development plans, we plan to leverage the development investments to date in our KL_4 surfactant and aerosol technology programs to address respiratory critical care conditions in older children and adults, including potentially ALI.

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. As a result of the number and nature of these factors, many of which are outside our control, the success, timing of completion and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. Certain of the risks and uncertainties affecting our ability to estimate projections and timelines are discussed in the Risk Factors Section and elsewhere in this Quarterly Report on Form 10-Q and in our 2012 Form 10-K, including in “Item 1 – Business – Government Regulation,” “Item 1A – Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Research and Development Expenses.”

Our lead development projects have been initially focused on the management of RDS in premature infants, including (i) SURFAXIN liquid instillate, and our lyophilized KL_4 surfactant, which we are developing initially for use in our AEROSURF development program and, potentially, in a SURFAXIN LS development program; and (ii) our aerosol delivery technology, including preparation of a clinic-ready CAG device to support our planned AEROSURF phase 2 clinical program. These and our other product programs are described in “– Overview – Business and Pipeline Programs Update,” and in our other periodic filings with the SEC, including our 2012 Form 10-K, “Item 1 – Business – Proprietary Platform – Surfactant and Aerosol Technologies,” and “- Surfactant Replacement Therapy for Respiratory Medicine.”

With respect to activities in support of our AEROSURF development program, from the beginning of 2012 through September 2013, we invested approximately $7 million to develop the CAG and complete the technology transfer and further develop our lyophilized KL_4 surfactant manufacturing process at DSM, in preparation for initiation of the phase 2 AEROSURF program. In addition, as noted above, we anticipate that direct clinical program costs associated with conducting the AEROSURF phase 2 clinical program will be approximately $8 -10 million through the completion of phase 2b in 2015.

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

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Selling, General and Administrative Expenses	$ 4,299	$ 4,255	$ 12,648	$ 9,912

Selling, general and administrative expenses consist primarily of the costs of executive management, commercial development, including marketing and field-based sales, business development, intellectual property, finance and accounting, legal, human resources, information technology, facility and other administrative costs.

Selling, general and administrative expenses for the nine months ended September 30, 2013 increased $2.7 million compared to the same periods in 2012, primarily due to increased investments in our marketing and field-based sales organization and related marketing expenses in preparation for the commercial introduction of SURFAXIN and the AFECTAIR device for infants.

In addition to developing our commercial marketing and sales organization, we have made additional investments to enhance certain of our general and administrative resources, including in legal, finance and accounting, and information technologies, to support the commercial introduction of our products.

Change in Fair Value of Common Stock Warrant Liability

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Change in fair value of common stock warrant liability (Income / (Expense))	$ (1,059)	$ (3,309)	$ 1,627	$ (5,063)

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), as either 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*, Notes 5 and 7 to our Consolidated Financial Statements in this Quarterly Report on Form 10-Q, and our 2012 Form 10-K, "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."

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

Interest Expense

The table below summarizes interest expense for the periods presented:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Interest Expense	$ (353)	$ (4)	$ (873)	$ (12)

Interest expense in 2013 consists of interest expense associated with the Deerfield Facility (*see*, "– Liquidity and Capital Resources – Loan Facility with Deerfield") and interest expense incurred under our equipment financing facilities. Interest expense for 2012 consists of interest expense incurred under our equipment financing facilities.

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Cash interest expense	$ 221	$ –	$ 551	$ –
Non-cash amortization of debt discounts	125	–	302	–
Amortization of debt costs	5	–	13	–
Total Deerfield Facility interest expenses	$ 351	$ –	$ 866	$ –

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

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have incurred substantial losses since inception, due to investments in research and development, manufacturing and potential commercialization 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 equity programs, and capital equipment financings.

As of September 30, 2013, we had cash and cash equivalents of $21.2 million, approximately $6.6 million of accounts payable and accrued expenses, and $10 million of long-term debt under our Deerfield Facility with Deerfield Management Company, L.P. (Deerfield).

On October 15, 2013, we completed an offering under our At-the-Market Program (ATM Program) (*see*, "– Common Stock Offerings – At-the-Market Program") with Stifel, Nicolaus & Company, Incorporated (Stifel) and issued 713,920 shares of our common stock resulting in net proceeds to us (after deducting commissions due to Stifel) of approximately $1.9 million. Through our ATM Program, subject to market conditions, we have the ability to sell up to approximately $23 million of common stock at such times and in such amounts that we deem appropriate. However, use of the ATM Program is subject to market and other conditions and the ATM Program can be cancelled at any time by either party. There can be no assurance that the ATM Program will be available when needed, if at all.

On November 5, 2013, we completed a public offering of 25 million shares of common stock, at a price of $2.00 per share resulting in gross proceeds of $50.0 million ($46.8 million net after commissions, discounts and expenses). In addition, we also granted the underwriters a 30-day option to purchase up to an additional 3.75 million shares of common stock (over-allotment) at an offering price of $2.00 per share. On November 8, 2013, we received notification that the underwriters have exercised the full over-allotment and will purchase an additional 3.75 million shares. This transaction is expected to close on or about November 14, 2013 and result in additional net proceeds to us of approximately $7.1 million.

We also have met the conditions for, and expect in early December to receive, an additional advance of $20 million under the Deerfield Facility, which became due upon the first commercial sale of SURFAXIN drug product. *See*, "– Loan Facility with Deerfield."

Before any additional financings, including under our ATM Program and taking into account the additional approximately $7.1 million expected from the underwriters' exercise of the over-allotment in our November public offering and the expected $20 million advance under the Deerfield Facility, we anticipate that we will have sufficient cash available to support our operations and debt service obligations through 2015.

Our future capital requirements depend upon many factors, primarily the success of our efforts to (i) execute the commercial introduction of SURFAXIN and AFECTAIR in the U.S., as planned; (ii) advance the AEROSURF development program to completion of the phase 2 clinical program in mid-2015; and (iii) secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, the commercial introduction of SURFAXIN, AEROSURF, AFECTAIR and potentially SURFAXIN LS, in markets outside the U.S. We believe that, if we are successful with the commercial introduction of SURFAXIN and if we are able to complete the AEROSURF phase 2 clinical program on a timely basis and obtain encouraging results, our ability to enter into a significant strategic alliance will be enhanced. There can be no assurance, however, that our efforts will be successful, or that we will be able to obtain additional capital to support our activities when needed on acceptable terms, if at all.

Even if we succeed with the commercial introduction of SURFAXIN and the AFECTAIR device as planned, given the time required to secure formulary acceptance of SURFAXIN at our target hospitals, we expect our revenues from SURFAXIN and AFECTAIR to be modest in the first 12-18 months and then increase over time as our products gain hospital acceptance. As a result, our cash outflows for operations, debt service and development programs are expected to outpace the rate at which we may generate revenues for several years. To execute our business strategy and fund our operations over the long term, we will require significant additional infusions of capital until such time as the net revenues from SURFAXIN, AFECTAIR and, if approved, AEROSURF, from potential strategic alliances and from other sources are sufficient to offset our cash flow requirements. To secure the necessary capital, we would prefer to enter into strategic alliances or collaboration agreements with partners that could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) and introduce our approved products in various markets outside the U.S. We also plan to consider other public and private equity offerings, including under our ATM Program, as well as other financing transactions, such as secured equipment financing facilities or other similar transactions.

As of September 30, 2013, we had outstanding warrants to purchase approximately 10.3 million shares of our common stock at various prices, exercisable on different dates through 2019. Of these warrants, approximately 2.3 million warrants were issued to Deerfield in connection with the first advance under the Deerfield Facility. Upon receipt of the final $20 million advance under the Deerfield Facility, which is anticipated on or about December 3, 2013, we will issue warrants to purchase an additional 4.66 million shares of our common stock at an exercise price of $2.81 per share (we refer to these warrants and the warrants previously issued to Deerfield as the 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 to purchase approximately 4.9 million shares of common stock that were issued in February 2011, are exercisable for five-years, and contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. These warrants were originally issued with an exercise price of $3.20 per share and thereafter adjusted downward, first to $2.80 per share following a public offering in March 2012 and then to $1.50 per share following a public offering in May 2013. Although we believe that, in the future, we will secure additional capital from the exercise of at least a portion of our outstanding warrants, there can be no assurance that the market price of our common stock will equal or exceed price levels that make exercise of outstanding warrants likely, or, even if the price levels are sufficient, that holders of our warrants will choose to exercise any or all of their warrants prior to the warrant expiration date. 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, 2013, 150 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, and approximately 71.7 million shares of common stock were available for issuance and not otherwise reserved. As of November 8, 2013, following the financings under our ATM Program, our public offering, and establishment of additional reserves for the shares expected to be issued in connection with the underwriters' exercise of the over-allotment in our November public offering and with respect to the warrants expected to be issued to Deerfield upon receipt of the $20 million advance in early December, approximately 42 million shares of common stock were available for issuance and not otherwise reserved.

Although we currently believe that we will be able to execute our business plan and accomplish our objectives, there can be no assurance that we will be successful. There can be no assurance that we will be successful in securing the needed capital, through strategic alliances, collaboration arrangements, financings, debt arrangements and other transactions. Failure to secure the necessary additional capital would have a material adverse effect on our business, financial condition and results of operations.

Cash Flows

As of September 30, 2013, we had cash and cash equivalents of $21.2 million compared to $26.9 million as of December 31, 2012. Cash outflows before financings for the nine months ended September 30, 2013 consisted of $30.4 million used for ongoing operating activities and $0.2 million for purchases of property and equipment. Cash outflows before financings were offset by a $10 million ($9.9 million net of expenses) advance in February 2013 under the Deerfield Facility and $15.1 million of net proceeds from a registered public offering that we completed in May 2013.

Operating Activities

Net cash used in operating activities was $30.4 million and $23.8 million for the nine months ended September 30, 2013 and 2012, respectively.

Net cash used in operating activities is the result of our net loss for the period adjusted for non-cash items associated with the change in fair value of common stock warrants (income of $1.6 million in 2013 and expense of $5.1 million in 2012), stock-based compensation, including our 401(k) match, and depreciation and amortization expenses ($2.9 million in 2013 and $2.7 million in 2012); and changes in working capital.

The increase in net cash used in operating activities from 2012 to 2013 is primarily due to (i) investment in our own specialty commercial and medical affairs organizations that are specialized in neonatal/pediatric respiratory critical care in NICUs/PICUs across the U.S., and manufacturing and quality activities in preparation for the commercial introduction of SURFAXIN and the AFECTAIR device for infants; (ii) costs to develop and manufacture clinic-ready CAGs for use in our planned AEROSURF phase 2a clinical study, including work with third party device experts and work that we began in June 2012 with Battelle, which is assisting with design, testing, and manufacture of clinic-ready CAG devices; and (iii) purchases of APIs used in the production of SURFAXIN and our lyophilized KL4 surfactant, for commercial purposes, development activities, including preparation of our CAG for use in our anticipated AEROSURF phase 2 clinical program, and to support the technical transfer of our manufacturing processes to our CMO.

Investing Activities

Net cash used in investing activities represents capital expenditures of $0.2 million and $0.6 million for the nine months ended September 30, 2013 and 2012, respectively.

Financing Activities

Net cash provided by financing activities was $24.9 million and $50.3 million for the nine months ended September 30, 2013 and 2012, respectively, summarized as follows:

(in thousands)	Nine Months Ended September 30, 2013	2012
Financings pursuant to common stock offerings	$ 15,114	$ 42,145
Issuance of long-term debt, net of expenses	9,850	–
Financings under the ATM Program	–	1,460
Repayment of equipment loans and capital lease obligations	(56)	(57)
Exercise of stock options and warrants	1	6,741
Cash flows from financing activities, net	$ 24,909	$ 50,289

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 June 2011, we filed a universal shelf registration statement on Form S-3 (No. 333-174786) (2011 Universal Shelf) with the SEC for the proposed offering from time to time of up to $200 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 that time. The 2011 Universal Shelf replaced an earlier shelf registration statement that was declared effective by the SEC on June 21, 2008. As of September 30, 2013, approximately $68.5 million remained available under the 2011 Universal Shelf. As of November 8, 2013, following the financings under our ATM Program and our public offering and establishment of a reserve related to the anticipated issuance of shares in connection with the underwriters' exercise of the over-allotment, we had approximately $11 million available under the 2011 Universal Shelf.

Registered Public Offerings

On May 15, 2013, we completed a registered public offering of 9.5 million shares of our common stock, at a price of $1.50 per share resulting in gross proceeds of $14.3 million ($13.2 million net). We also granted the underwriter a 30-day option to purchase up to an additional 1.425 million shares of common stock at an offering price of $1.50 per share. On May 31, 2013, the underwriter exercised its option and purchased 1.347 million additional shares of common stock for net proceeds to us (after underwriter fees) of $1.9 million. In connection with this offering, we agreed not to issue or sell (with certain limited exceptions) securities for a period of 90 days after the date of the prospectus supplement ending August 8, 2013. Regarding our ATM Program, we agreed not to issue or sell securities for a period of 30 days after the date of the underwriting agreement ending on June 9, 2013.

On November 5, 2013, we completed a registered public offering of 25 million shares of our common stock, at a price of $2.00 per share resulting in gross proceeds of $50.0 million ($46.8 million net after commissions, discounts and expenses). In addition, we also granted the underwriters a 30-day option to purchase up to an additional 3.75 million shares of our common stock at a public offering price of $2.00 per share. In connection with this offering, we agreed not to issue or sell (with certain limited exceptions) securities for a period of 90 days after the date of the prospectus supplement ending February 3, 2014. Regarding our ATM Program, we agreed not to issue or sell securities for a period of 30 days after the date of the underwriting agreement ending on December 5, 2013. On November 8, 2013, we received notification that the underwriters have exercised the full over-allotment and will purchase an additional 3.75 million shares. This transaction is expected to close on or about November 14, 2013 and result in additional net proceeds to us of approximately $7.1 million.

At-the-Market Program

In February 2013, we entered into an At-the-Market Equity Offering Sales Agreement with 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. 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*, Note 17, “Subsequent Events – ATM Program,” to the consolidated financial statements in our 2012 Form 10-K.

On October 15, 2013, we completed an offering under our ATM Program and issued 713,920 shares of our common stock for an aggregate purchase price of approximately $2.0 million, resulting in net proceeds to us of approximately $1.9 million, after deducting commissions due to Stifel. As of November 8, 2013, approximately $23 million shares of common stock remained available under the ATM Program.

Committed Equity Financing Facility (CEFF)

We had a Stock Purchase Agreement dated June 11, 2010 (CEFF) with Kingsbridge Capital Limited (Kingsbridge) that provided initially for the purchase by Kingsbridge of the lesser of up to 2.1 million shares of our common stock or a maximum of $35 million in shares. We were not obligated to issue shares at any time. This CEFF expired on June 11, 2013 with 1.1 million shares available but not issued. *See*, “2012 Form 10-K – Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility (CEFF).”

Loan Facility with Deerfield

On February 13, 2013, we entered into a secured loan facility (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield) for up to $30 million in secured financing in 2013. Deerfield advanced to us $10 million upon execution of the agreement and agreed to advance an additional $20 million, subject to certain conditions, on or about the date of the first commercial sale of SURFAXIN drug product (Milestone Date), if the Milestone Date occurs on or before December 31, 2013. On November 8 2013, we notified Deerfield that the first commercial sale of SURFAXIN has occurred, and anticipate receipt of the $20 million advance on or about December 3, 2013.

The loan may be prepaid in whole or in part without penalty at any time. Any amounts received and outstanding under the Deerfield Facility will accrue interest at a rate of 8.75%, payable quarterly in cash. *See*, “– Note 6, Long-term Debt – Loan Facility with Deerfield,” to the Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q, for a description of the terms and conditions of the Deerfield Facility agreement and terms of the Deerfield Warrants.

We have recorded the loan as long-term debt at its face value of $10.0 million less debt discounts and issuance costs consisting of (i) $3.8 million fair value of warrants that we issued to Deerfield in connection with the $10 million initial advance, to purchase approximately 2.3 million shares at an exercise price of $2.81, and (ii) a $150,000 transaction fee. The discount is being accreted to the $10 million loan over its term using the effective interest method. The Deerfield Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC 815 and are classified as equity.

Long-term debt as of September 30, 2013 consists solely of amounts due under the Deerfield Facility as follows:

Note Payable	$ 10,000
Unamortized discount	(3,674)
Long-term debt, net of discount	$ 6,326

Contractual Obligations and Commitments

Future payments due under contractual obligations at September 30, 2013 are as follows:

(in thousands)	2013	2014	2015	2016	2017	There-after	Total
Operating lease obligations	$ 272	$ 1,087	$ 1,024	$ 934	$ 935	$ 158	$ 4,410
Deerfield Loan Facility[1]	–	–	–	–	3,330	6,670	10,000
Equipment loan obligations	13	79	69	–	–	–	161
Total	$ 285	$ 1,166	$ 1,093	$ 934	$ 4,265	$ 6,828	$ 14,571

(1) *See*, "– Loan Facility with Deerfield"

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash and cash equivalents. We place our investments with high quality issuers and, by policy, we have limits as to the amount of credit exposure to any one issuer. We do not hedge interest rate or currency exchange exposure and do not use derivative financial instruments for speculation or trading purposes. We classify highly liquid investments purchased with a maturity of three months or less as "cash equivalents." Loans under our Deerfield Facility have a fixed interest rate of 8.75%. Because of the fixed rate, a change in market interest rates would not have a material impact on interest expense associated with the loan.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

Our management, including our President and Chief Executive Officer and Chief Financial Officer (principal executive officer and financial officer), does not expect that our disclosure controls and procedures 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 Chief Financial Officer has 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 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 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 controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) under the Exchange Act that occurred during the quarter ended September 30, 2013, that have materially affected, or are 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 2012 Form 10-K, as supplemented by the risks and uncertainties discussed below and elsewhere in this Quarterly Report on 10-Q. If any of the risks and uncertainties set forth below or in our 2012 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 risks and uncertainties set forth below and discussed elsewhere in this Quarterly Report on Form 10-Q and described in our 2012 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 immaterial may also impair our business operations.

Even if we succeed with the commercial introduction of SURFAXIN® as planned, we nevertheless in the future will require, but may be unable to secure when needed, significant additional capital to continue our operations, pay our debt service, and commercialize our approved products and develop our products under development, including our AEROSURF® phase 2 clinical program, and to continue our other research and development programs. Moreover, any financings could result in substantial dilution to our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2013, we have an accumulated deficit of approximately $468.2 million and we expect to continue to incur significant, increasing operating losses over the next several years. As of September 30, 2013, we had cash and cash equivalents of approximately $21.2 million and approximately $6.6 million of accounts payable and accrued expenses and $10 million of long-term debt under the Deerfield Facility. In October, we completed an offering under our ATM Program that resulted in net proceeds to us of approximately $1.9 million. On November 5, 2013, we completed a public offering that resulted in net proceeds to us of approximately $46.8 million and granted the underwriters an option to purchase an additional 3.75 million shares (the over-allotment). The over-allotment was exercised in full and, on or about November 14, 2013, we anticipate receipt of an additional approximately $7.1 million. On November 8, 2013, we announced that we have initiated the commercial launch of SURFAXIN and notified Deerfield that we had met the requirements to receive the additional $20 million available under the Deerfield Facility. Before any additional financings, including under our ATM Program and taking into account the expected $20 million advance under the Deerfield Facility and the $7.1 million expected in connection with the over-allotment, we anticipate that we will have sufficient cash available to support our operations and debt service obligations through 2015.

We expect to continue to spend substantial amounts to execute our business strategy and will require significant additional infusions of capital until such time as the net revenues from SURFAXIN and, if approved, AEROSURF, and from potential strategic alliance and collaboration arrangements and other sources, are sufficient to offset our cash flow requirements. Given the time required to secure formulary acceptance of SURFAXIN, we expect our revenues from SURFAXIN to be modest in the first 12-18 months and then increase over time. Our investments in our operations, debt service and development programs are expected to outpace the rate at which we may generate revenues for several years. *See*, "Part 1, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our products or our research and development programs. We also could be required to:

- seek collaborators for one or more of our development programs for territories that we had planned to retain or on terms that are less favorable than might otherwise be available; and/or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to secure such financing, we may seek additional capital from the public markets, which could have a dilutive impact on our stockholders and the issuance, or even potential issuance, of shares could have a negative effect on the market price of our common stock.

Depending on conditions in the global financial markets, we may face significant challenges accessing the capital markets at a time when we would like or require, and at an increased cost of capital. Except for our ATM Program, we do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. In any such event, the market price of our common stock may decline. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could delay new product development and clinical trial plans.

Our near-term prospects are highly dependent on the success of SURFAXIN. To the extent we fail to successfully commercialize SURFAXIN, or if our efforts to commercialize SURFAXIN are significantly delayed, our business, financial condition and results of operations would be materially adversely affected and the price of our common stock would likely decline.

In March 2012, the FDA approved SURFAXIN. Following a period in which we updated product specifications and improved an analytical chemistry method, in October 2013, we received a communication from the FDA that it agreed with our updates. We immediately manufactured SURFAXIN drug product and have initiated the commercial introduction of SURFAXIN in our target hospitals. We believe that SURFAXIN product sales may constitute substantially all or most of our total revenue over the next several years.

We currently believe that we will successfully execute the commercial introduction of SURFAXIN within our anticipated timeframe. However, our efforts are subject to a variety of risks and uncertainties that could cause actual results to be materially different.

If we successfully make our products commercially available, the commercial success of SURFAXIN and our ability to generate and increase revenues will depend on a number of factors, including the following:

- the number of hospitals and critical care centers that agree to place SURFAXIN drug product on their formulary lists and the length of time required to achieve broad formulary acceptance;
- the willingness of the target hospitals to accept and employ WARMING CRADLE® dry-block heater;
- the effectiveness of our marketing, sales and medical affairs organizations and their ability to (a) accurately describe SURFAXIN consistent with its approved labeling, and (b) educate and provide critical care providers and hospitals with medical and scientific education and information concerning our products;
- our ability to gain access to the entire market with our commercial organizations;
- the safety and efficacy of SURFAXIN, our ability to provide hospitals acceptable evidence of the safety and efficacy of SURFAXIN, and the perceived advantages of SURFAXIN over alternative treatment methods;

- the pharmacoeconomic benefits (which are determined by comparing, among other things, the cost and effects of a product when compared to different treatment options) and cost-effectiveness of our products;
- the budget impact of adding our products and devices to relevant formulary and medical device hospital lists and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs and other competitive products;
- the availability of different size drug vials and medical devices to meet the specific needs of healthcare practitioners;
- the claims, limitations, warnings and other information that appear in the package insert and labeling of SURFAXIN drug product;
- the willingness of third-party payers, including government payers, to provide coverage and reimbursements to patients, physicians and other providers who wish to prescribe and use our products;
- our ability to secure and maintain regulatory marketing approvals from the U.S. and foreign regulatory authorities;
- the rate of preterm births;
- the number of infants who are diagnosed with RDS and the number treated with SURFAXIN;
- the growth of commercial sales;
- our ability to meet commercial demand for SURFAXIN, including through maintenance of commercial supplies of our active drug substances and other excipients, and manufacturing capabilities, by ourselves and through third-party manufacturers; and commercial inventory supplies of our medical device products; and
- the sufficiency of coverage or reimbursement by third parties.

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. SURFAXIN is approved for marketing only in the U.S. We cannot predict whether physicians, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize SURFAXIN and our other products and devices, if approved. If we are not successful in our efforts to gain broad acceptance of SURFAXIN in our target hospitals, the revenues we generate from sales will be limited and our business may not be profitable.

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 will harm our business.

The FDA has completed its review and cleared our IND for our AEROSURF® phase 2 clinical program. This initial clinical study is the first in a series of clinical studies that will be needed to gain marketing authorization for AEROSURF. Such clinical programs generally 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 studies necessary for approval, or we may be unable to reach agreement on a single study design that would permit us to conduct a single clinical program. Conditions imposed by the FDA and foreign regulators on our clinical studies could significantly increase the time required for completion of such clinical studies and the costs of conducting the clinical studies. For example, we may not be successful in achieving a study design that is acceptable to the FDA and regulators in other countries, which would cause us to greatly increase our investment or limit the scope of our activities. Like many biotechnology companies, even after obtaining promising results in earlier studies or in preliminary findings for such clinical studies, we may suffer significant setbacks in late-stage clinical studies. Data obtained from clinical studies are 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 studies. The timing and completion of current and planned clinical studies of our product candidates depend on many factors, including the rate at which patients are enrolled. Delays in patient enrollment in clinical studies 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 studies;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

If we succeed in achieving our patient enrollment targets, patients that enroll in our clinical studies could suffer adverse medical events or side effects that are known, such as a decrease in the oxygen level of the blood upon administration, or currently unknown to us. It is also possible that we, our AEROSURF Clinical Trial (ACT) Steering Committee, the Safety Review Committee (SRC), or the FDA could interrupt, delay or halt any one or more of our clinical studies for any of our product candidates. If our ACT Steering Committee, the SRC, any regulator or we believe that study participants face unacceptable health risks, any one or more of our studies could be suspended or terminated. In addition, clinical studies 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.

In addition to our planned clinical programs to support AEROSURF, in the future, we also may initiate or support clinical studies evaluating other KL_4 surfactant pipeline products. All of these clinical studies 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.

Our manufacturing strategy includes relying, at least in part in the future, on third parties to manufacture our current approved products as well as certain of our drug product candidates and medical devices, which exposes us to risks that may affect our ability to maintain supplies of our commercial products and/or delay our research and development activities, regulatory approval and commercialization of our drug product candidates.

We currently manufacture our SURFAXIN liquid instillate at our operations located in Totowa, New Jersey. Our strategy includes potentially manufacturing SURFAXIN drug product in the future and our lyophilized dosage form of our KL_4 surfactant, as well as our CAG and AFECTAIR devices, using third-party contract manufacturing organizations (CMOs). Our planned future reliance on CMOs exposes us, among other things, to the following risks:

- we may be unable to successfully identify manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all, because the number of potential manufacturers is limited and the FDA must approve any replacement CMO. This approval could take as long as a year and would require new testing and compliance inspections as well as a potentially lengthy qualification process;
- CMOs might be unable to manufacture our products in the volume and to our specifications to meet our commercial and clinical needs, or we may have difficulty scheduling the production of drug product and devices in a timely manner to meet our timing requirements;
- CMOs may not perform as agreed, or may not remain in the CMO business for a lengthy time, or may refuse to renew an expiring agreement as expected, or may fail to product a sufficient supply to meet our commercial and/or clinical needs;
- CMOs are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with cGMP and/or quality system regulations (QSR) and other government regulations and corresponding foreign standards. We do not have control over CMO's compliance with these regulations and standards;
- moreover, if we desire to make our drug products and/or devices available outside the U.S. for commercial or clinical purposes, our CMOs would become subject to, and may not be able to comply with, corresponding manufacturing and quality system regulations of the various foreign regulators having jurisdiction over our activities abroad. Such failures could restrict our ability to execute our business strategies;
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not have rights to, or may have to share, the intellectual property rights to any such innovation. We may be required to pay fees or other costs for access to such improvements; and
- each of these risks could delay our commercial manufacturing plans and our development programs, the approval, if any, of our product candidates by the FDA or result in higher costs or deprive us of potential product revenues.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

As we prepared for the commercial introduction of SURFAXIN, we implemented a plan to hire additional qualified personnel to support (i) the commercial introduction of SURFAXIN and AFECTAIR, and (ii) the advancement of our AEROSURF and SURFAXIN LS development programs. In particular, we established our field-based sales and marketing and medical affairs organizations, and continue to invest in our regulatory affairs, quality control and assurance and administrative capabilities. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is significant and attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us.

We are highly dependent upon the members of our executive management team and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these individuals have been involved with us for many years, have played integral roles in our progress and we believe that they continue to provide value to us. A loss of any of our key personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs.

In March 2013, we entered into employment agreements with five executive officers, including the President and Chief Executive Officer and Chief Financial Officer; the Senior Vice President and Chief Operating Officer; the Senior Vice President, General Counsel and Corporate Secretary; the Senior Vice President, Human Resources; and the Senior Vice President, Research and Development. These agreements expire on March 31, 2015, subject to automatic renewal for additional one-year periods, unless a party provides notice of non-renewal at least 90 days in advance. In addition, we recently entered into new agreements with five other officers that also expire on March 31, 2015. The loss of services from any of our executives could significantly adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key man life insurance.

As we prepare for the commercial introduction of our approved products and to initiate our AEROSURF phase 2 clinical program, we need to attract and retain highly-qualified personnel to join our management, commercial, medical affairs and development teams, although there can be no assurances that we will be successful in that endeavor. We may be unable to attract and retain necessary executive talent.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel. While we attempt to provide competitive compensation packages to attract and retain key personnel at all levels in our organization, many of our competitors have greater resources and more experience than we do, making it difficult for us to compete successfully for key personnel. We may experience intense competition for qualified personnel and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to lawsuits brought by their former employers.

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

During the nine months ended September 30, 2013, we issued an aggregate of 23,750 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during 2013. The shares were issued as follows: 7,500 shares on each of February 28, 2013, and May 31, 2013, and 8,750 shares on August 31, 2013. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(2) of the Act.

ITEM 6. EXHIBITS

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

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: November 12, 2013

By: /s/ John G. Cooper
John G. Cooper
President and Chief Executive Officer and Chief Financial Officer
(Principal Executive and 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 of Discovery Laboratories, Inc. (Discovery) filed as of August 1, 2013, including amendments reflected in a Certificate of Amendment to the Restated Certificate of Incorporation of Discovery filed on December 27, 2010, and in a Certificate of Amendment to the Restated Certificate of Incorporation of Discovery filed on October 3, 2011	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, as filed with the SEC on August 8, 2013.
3.2	Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004	Incorporated by reference to Exhibit 2.2 to Discovery's Form 8-A, as filed with the SEC on February 6, 2004.
3.3	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	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 6, 2004.
4.2	Warrant Agreement dated May 22, 2008 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 May 28, 2008.
4.3	Warrant Agreement dated December 12, 2008 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 December 15, 2008.
4.4	Form of Stock Purchase Warrant issued in May 2009	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on May 8, 2009.
4.5	Form of Stock Purchase Warrant 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.
4.6	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.
4.7	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.

Exhibit No.	Description	Method of Filing
4.8	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.
4.9	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.
4.10	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.
4.11	Form of Series II Warrant to Purchase Common Stock issued on February 22, 2011	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 16, 2011.
4.12+	Form of Warrant issued to Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P. (collectively, Deerfield) under a Facility Agreement dated as of February 13, 2013 between Discovery and Deerfield (Deerfield Facility)	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
4.13	Form of Notes issued to Deerfield evidencing loan under Deerfield Facility	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.1	Extension, dated as of July 16, 2013, of Lease dated as of December 3, 2004, between Discovery, as successor-in-interest to Laureate Pharma, Inc. (Tenant), and Norwell Land Company ("Landlord"), with respect to property at 710 Union Blvd., Totowa, NJ 07512	Incorporated by reference to Exhibit 10.1 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, as filed with the SEC on August 8, 2013.
10.2+	Pharmaceutical Manufacturing and Supply Agreement dated August 7, 2013 between Discovery and DSM Pharmaceuticals, Inc. (DSM)	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, as filed with the SEC on August 8, 2013.
10.3+	Master Services Agreement dated October 24, 2013 between Discovery and DSM	Filed herewith.
31.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith.

Exhibit No.	Description	Method of Filing
101.1	The following consolidated financial statements from the Discovery Laboratories, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of September 30, 2013 (unaudited) and December 31, 2012, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2013 and September 30, 2012, (iii) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2013 and September 30, 2012, and (v) Notes to consolidated financial statements.	
101.INS	Instance Document	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

+ Confidential treatment requested as to certain portions of this exhibit. Such portions have been redacted and filed separately with the Commission.

EXHIBIT 10.3

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [***]

MASTER SERVICES AGREEMENT

This Master Services Agreement (this "Agreement"), dated as of October 24, 2013 (the "Effective Date"), is by and between **DSM Pharmaceuticals, Inc.**, 5900 Martin Luther King Hwy., Greenville NC 27834 ("DSM"), and **Discovery Laboratories, Inc.**, 2600 Kelly Road, Suite 100, Warrington, PA 18976-3622 ("Discovery Labs") (each individually a "Party" and collectively, the "Parties), with respect to the continuing development and manufacture of preclinical and clinical supplies of Discovery Labs' lyophilized KL4 surfactant (the "Product") for use in one or more of Discovery Labs' products.

Background

Discovery Labs previously initiated a technology transfer to DSM of Discovery Labs' manufacturing processes and know-how related to Discovery Labs' Product. The Parties now wish to confirm their plans and expectations related to the further development and manufacture of the Product.

1. Scope and Purpose. This Agreement is intended to provide for a basic framework under which DSM will perform certain development and manufacturing activities related to the Product, as may be requested by Discovery Labs and agreed by DSM from time to time, including but not limited to: (i) equipment procurement and installation, (ii) validation master plan, (iii) regulatory support, (iv) quality assurance support, (v) manufacture of engineering lots and development lots to support Discovery Labs' preclinical, clinical, research and development activities, (vi) potential scale up activities and (vii) potential manufacture of process validation lots (the "Services").

2. Statements of Work. All Services shall be performed pursuant to one or more Statements of Work ("SOW") attached to this Agreement from time to time, in a form to be mutually agreed between the Parties. Each SOW shall contain a description of the Services to be performed, including any information or other materials to be delivered, the price to be paid by Discovery Labs to DSM for the Services, any equipment specially required for the Services for which DSM is authorized to purchase for which Discovery Labs will reimburse DSM, and such other terms and conditions that are consistent with this Agreement to which the Parties may agree. The Parties agree that DSM will perform any mutually agreed upon Services for Discovery Labs as more fully described in the relevant Statement of Work developed and entered into by the Parties. By mutual agreement of the Parties, such SOW may be amended, including to change, extend, or expand the scope of Services provided such amendment is expressly stated in a writing and signed by authorized representatives of the Parties. Each SOW shall be effective when signed by authorized representatives of both Parties, and will be subject to the terms of this Agreement. In the event of a conflict between the terms of a SOW and the terms of this Agreement, the terms of this Agreement shall govern.

3. Cost of Services.

(A) Discovery Labs shall pay to DSM the cost of the Services as set forth in the applicable SOW, as well as the anticipated cost of all chemicals and other materials.

(B) Unless otherwise provided in a SOW, active pharmaceutical ingredients ("APIs") to be used hereunder shall be procured by Discovery Labs and provided by Discovery Labs to DSM at Discovery Labs' sole expense.

(C) Discovery Labs shall separately pay DSM, on an as-costs-are-incurred basis (i) for all reasonable and necessary travel and lodging expenses incurred in the performance of this Agreement which have been requested or approved by Discovery Labs in writing, (ii) for DSM's cost of auditing any supplier of chemicals or materials not currently on DSM's list of approved suppliers, and (iii) the cost of any specialized equipment or tooling associated with equipment changes required at DSM's facility to perform the Services; provided, that any such costs shall be specified in writing in sufficient detail and their incurrence must be authorized in writing in advance by Discovery Labs.

(D) DSM is authorized to purchase equipment (the "Equipment") which is specially required for the performance of the Services as may be set forth in a SOW from time to time; provided that (i) an Equipment Purchase Order Addendum shall be entered into by the Parties in connection therewith substantively in the form attached hereto as Addendum I; and (ii) such Equipment shall be used solely in furtherance of the Services and not for any other purposes whatsoever without the prior written consent of Discovery Labs. Discovery Labs will authorize purchase of items of Equipment according to a Purchase Order or other written confirmation from Discovery Labs to DSM; and shall reimburse DSM for its reasonable costs for the purchase and installation of such Equipment. DSM shall obtain Discovery Labs' prior written approval for all costs and expenses associated with the installation and qualification of Equipment (including without limitation labor and engineering costs) purchased by Discovery Labs and Discovery Labs shall reimburse DSM for all such reasonable costs according to the payment terms in Section 7.

(E) Any sales, use, consumption, or excise taxes of any taxing authority which are imposed upon the Product or Services supplied hereunder shall be reimbursed to DSM by Discovery Labs.

4. Purchase Orders.

(A) Except to the extent the Parties may otherwise agree with respect to a particular shipment, all Product shall be ordered by Discovery Labs pursuant to written Purchase Order ("Purchase Order"), specifying the quantity and desired delivery dates, and shall be sent to DSM not less than [***] prior to the delivery date specified in such Purchase Order. The Parties shall negotiate in good faith to resolve any issues regarding delivery dates if DSM is unable to schedule production at the requested time.

(B) Any additional or conflicting terms and conditions which may be printed on Purchase Orders issued by Discovery Labs shall have no force or effect between the Parties unless specifically agreed to by DSM.

(C) Discovery Labs will prepare, obtain, and maintain all necessary import and export registrations relating to the Product and the API. Discovery Labs represents and warrants that it will comply with all applicable import and export laws and regulations. If Discovery Labs elects to export Product to countries outside the United States, then Discovery Labs shall so advise DSM; and Discovery Labs shall be responsible for providing all necessary compliance information to DSM so that DSM can achieve compliance with the requirements of such additional countries.

5. Confidentiality and Public Announcements. Each Party acknowledges and agrees to maintain the confidentiality of preparations and negotiations undertaken in connection with the Services and the other Party's respective Confidential Information, in each event in accordance with the Mutual Confidential Disclosure Agreement between the Parties, dated as of October 13, 2010. Any trade secrets disclosed by Discovery Labs to DSM must be specifically identified as such. Neither Party will make any public announcement of any information regarding this Agreement or any activities thereunder including, without limitation, the Services, without the prior written approval of the other Party; provided, however, that each Party may disclose (i) the general existence of this Agreement and the arrangement between them, except to the extent that any such information constitutes Confidential Information, (ii) any information required by law (including information provided in connection with required public regulatory filings, public securities filings and private placement memoranda and documentation), and (iii) any other information that has been previously approved in writing for disclosure by the other Party, without further approval from the other Party. In addition, the Parties acknowledge that Discovery Labs intends to file in its public securities filings, including potentially in a Current Report on Form 8-K or Quarterly Report on Form 10-Q, a description of this Agreement and a copy of this Agreement. DSM agrees that Discovery Labs may submit a description of this Agreement and a copy of this Agreement in connection with its public securities filings, subject to the understanding that Discovery Labs will in good faith and in consultation with DSM, seek confidential treatment of Confidential Information or other proprietary provisions of this Agreement (including any pricing information or limits on liability) in advance of such filing. The Parties acknowledge, however, that while Discovery Labs will request confidential treatment of Confidential Information, Discovery Labs will be required to disclose any information determined to by applicable regulatory authorities to require disclosure. Except as expressly provided in this Section 5, no right is granted pursuant to this Agreement to either Party to use in any manner the name of the other Party.

6. Pharmaceutical Manufacturing and Supply Agreement. The Parties acknowledge and agree that upon successful conclusion of the Services and in the event Discovery Labs receives final marketing approval for the Product (from either the FDA or EMEA), and elects to proceed with the marketing of the Product, the Parties shall negotiate in good faith regarding terms of a long-term manufacturing supply agreement for the Product and may decide for the manufacture of such Product to be governed by the separate Pharmaceutical Manufacturing and Supply Agreement entered into between the Parties dated August 7, 2013 (in either case, the "Supply Agreement") for Discovery Labs' liquid KL_4 surfactant.

7. Payments. All payments due hereunder shall be invoiced to Discovery Labs by DSM on a net [***] basis from date of invoice. Overdue payments shall bear interest at the rate of [***] per month, pro-rated for any partial month, beginning with the day following the due date and continuing to the date of payment.

8. Discovery Labs' Responsibilities.

(A) To assist DSM in its performance of this Agreement, Discovery Labs shall provide DSM, in a timely fashion, with all relevant information, documentation and data (including without limitation information, any documentation and data relating to product safety and information) necessary or appropriate for DSM's performance hereunder.

(B) Discovery Labs shall ensure that all API supplied to DSM by or on behalf of Discovery Labs is suitable for use under this Agreement.

(C) Discovery Labs shall comply with all applicable laws and regulations and receive all required governmental and regulatory approvals, including without limitation customs and FDA approvals.

(D) Discovery Labs shall be responsible for disclosing to DSM all information available to it regarding health risks which may be involved in manufacturing the Product, including without limitation, industrial hygiene data, exposure limitations for workers involved in production, toxicology reports, and other health-related data. If reasonable industrial hygiene data is not available, DSM may develop reasonable data at Discovery Labs' expense.

9. DSM's Representations and Warranties. DSM represents, warrants and covenants to Discovery Labs as follows:

(A) DSM shall use its commercially reasonable efforts to perform the Services contemplated hereunder in accordance with the SOWs to be attached hereto from time to time. It is recognized and agreed by and between DSM and Discovery Labs, however, that since the Services are of a developmental or research nature, DSM hereby disclaims any warranties that the Services will be successfully completed, or successfully completed within the contemplated time period, despite DSM's commercially reasonable efforts to do so.

(B) DSM shall produce the Product in accordance with the Specifications as developed for the Product as set forth in the SOW. "Specifications" shall mean the specifications for the Product attached to a SOW as determined and agreed upon in accordance with a development program outlined in the SOW using analytical methodology set forth therein, as such specifications may be amended from time to time by mutual agreement of the Parties.

(C) DSM shall engage and employ professionally qualified personnel to perform the Services contemplated hereunder.

10. Limitation of Liability. **EXCEPT AS PROVIDED IN SECTION 9, DSM HEREBY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY OR WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCT. DISCOVERY LABS' ONLY REMEDY FOR BREACH OF THIS AGREEMENT SHALL BE** [***] **WHICH DID NOT COMPLY WITH THE REQUIREMENTS SET FORTH IN THIS AGREEMENT. ALL OTHER DAMAGES, INCLUDING DAMAGES FOR DELAYS, LOST PROFITS, LOST BUSINESS OPPORTUNITY, OR CONSEQUENTIAL, INDIRECT, AND PUNITIVE DAMAGES, ARE HEREBY EXPRESSLY EXCLUDED. THE PARTIES FURTHER AGREE THAT FOR INTENTIONAL BREACHES OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN SECTION 5 BY DSM THAT MATERIALLY HARM DISCOVERY LABS, DSM'S LIABILITY SHALL BE LIMITED TO** [***]**.**

11. Indemnification.

(A) Discovery Labs shall indemnify, defend and hold DSM, its Affiliates and their respective directors, officers, employees, agents, successors and assigns, harmless from and against any damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) arising out of or in connection with (a) the Services or the use, handling, distribution, marketing or sale of the Product by Discovery Labs or a third party (except to the extent caused solely by DSM's negligent acts or omissions or willful misconduct in its performance of the Services or the manufacture or labeling of the Product), (b) Discovery Labs' material breach of any of its obligations hereunder, (c) any third party claim of illness, injury, or death caused by the use of any Product manufactured by DSM hereunder in accordance with the Specifications; (d) any claim by any employee of DSM, its subcontractors, or any third party of illness, injury or death arising out of Discovery Labs' failure to inform DSM of health risks related to the Product; (e) any proceeding instituted by or on behalf of a third party based upon a claim that the manufacture, use or sale of the Product infringes a United States patent or any other proprietary rights claimed by Discovery Labs and utilized by DSM in the production of the Product; or (f) any act or omission of negligence, gross negligence, or willful misconduct by Discovery Labs or its respective directors, officers, employees, agents, or representatives.

(B) DSM shall indemnify, defend and hold Discovery Labs, its Affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) arising out of or in connection with (a) any third party claim arising solely out of DSM's material breach of any of its warranties or representations hereunder, (b) any proceeding instituted by or on behalf of a third party based upon a claim that DSM Intellectual Property infringes a United States patent or any other proprietary rights (except for such claims as are subject to indemnity by Discovery Labs as set forth above); or (c) any act or omission of negligence, gross negligence, or willful misconduct by DSM or its respective directors, officers, employees, agents, or representatives in the performance of the Services or the manufacture or labeling of the Product.

(C) A Party (the "Indemnitee") which intends to claim indemnification under this Section 10 shall promptly notify the other Party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees or agents intend to claim such indemnification; provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee, its Affiliates, and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation, negotiation, compromise, settlement and defense of any action, claim or other matter covered by this indemnification. The Indemnitor shall be in charge of and control of any such investigation, negotiation, compromise, settlement and defense, and shall have the right to select counsel with respect thereto, provided that the Indemnitor shall promptly notify the Indemnitee of all material developments in the matter. In no event shall the Indemnitor settle any such matter in a manner that involves an admission of guilt, liability, or wrongdoing by the Indemnitee, or that risks additional liability to the Indemnitee. In no event shall the Indemnitee compromise or settle any such matter without the prior written consent of the Indemnitor. In no event shall the Indemnitor compromise or settle any such matter without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; nor shall the non-consenting Party be bound by any such settlement. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

(D) The provisions of this Section 10 shall survive the expiration or termination of this Agreement.

(E) For purposes of this Agreement, "Affiliate" shall mean any corporation or non-corporate entity which directly or indirectly controls, is controlled by, or is under common control with a Party. A corporation or non-corporate entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least fifty percent (50%) of the voting stock of the other corporation; or (a) in the absence of the ownership of at least fifty percent (50%) of the voting stock of a corporation or (b) in the case of a non-corporate entity, the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable.

12. Term and Termination.

(A) The term of this Agreement shall commence on the Effective Date and continue until the later of (a) the third anniversary of the Effective Date, or (b) the date that work under all Statements of Work issued hereunder have been completed, unless the Parties mutually agree to extend this Agreement.

(B) This Agreement shall be terminated as follows:

(i) At any time by Discovery Labs upon [***] notice to the DSM. Unless otherwise specifically set forth herein or agreed by the Parties, termination of this Agreement pursuant to this Section 12(B)(i) shall not result in the termination of any SOW then in progress, and the terms of this Agreement shall apply to such SOW.

(ii) Once the parties enter into a Supply Agreement as referred to in Section 6 above, unless such Supply Agreement expressly provides that this Agreement shall continue in force and effect until certain Services are completed.

(iii) By either Party in the event of the material breach or default by the other Party of the terms and conditions hereof; provided, however, that the other Party shall first give to the defaulting Party written notice of the proposed termination or cancellation of this Agreement, specifying the grounds therefor. Upon receipt of such notice, the defaulting Party shall have [***] to respond by curing such default (or [***] with respect to a failure by Discovery Labs to pay any undisputed amounts hereunder when due) or by delivering to the other Party a certificate that such breach is not capable of being cured within such [***] and that the breaching Party is working diligently to cure such breach, but in no event shall the time period for curing such breach exceed an additional [***]. If the breaching Party does not so respond or fails to work diligently and to cure such breach within the additional time set forth above, then the other Party may terminate the Agreement.

(iv) By either Party upon (i) the entry of a decree or order for relief by a court having jurisdiction in the premises in respect of such Party in an involuntary case under the Federal Bankruptcy Code, as now constituted or hereafter amended, or any other applicable federal or state insolvency or other similar law and the continuance of any such decree or order unstayed and in effect for a period of [***]; or (ii) the filing by such Party of a petition for relief under the Federal Bankruptcy Code, as now constituted or hereafter amended, or any other applicable federal or state insolvency or other similar law.

(v) Either Party may terminate a particular SOW (i) if the Services are not progressing according to the expectations of Discovery Labs and DSM and Discovery Labs cannot agree on appropriate scope changes or additional financial costs associated with scope changes.

(vi) DSM may terminate a SOW and/or this Agreement (i) after [***] of inactivity on a project that is the subject of a SOW at Discovery Labs' request, or (ii) if DSM reasonably and in good faith determines that it is unable to perform the Services hereunder and/or manufacture the Product in a safe and effective way in accordance with applicable regulatory requirements (including OSHA and FDA regulations) and applicable Specifications.

(C) Upon termination of this Agreement or a SOW, Discovery Labs shall (i) pay DSM for all Services completed by DSM prior to or in connection with any such termination,(ii) pay DSM for any Equipment purchased by DSM at Discovery Labs' request, (iii) reimburse DSM for any inventories of materials purchased by DSM for use in the Services which remain unused as of the date of termination plus the costs to return or destroy such materials. In addition, upon termination of this Agreement, the obligations of confidentiality set forth in Section 5 shall continue as well as the indemnity obligations set forth in Section 11 In addition, DSM will provide reasonable assistance to Discovery Labs at Discovery Labs' cost in taking possession of the Equipment purchased or paid for by Discovery Labs and used by DSM in performing Services under this Agreement unless the Parties agree that such Equipment will continue to be used under the Supply Agreement or unless the Parties agree that DSM shall otherwise retain such Equipment.

(E) Upon termination of this Agreement or a SOW, the Parties shall agree on a plan whereby DSM agrees to provide reasonable cooperation and assistance with respect to the transfer of manufacturing technology applicable to the Product to Discovery Labs or its delegate to further manufacture the Product, such cooperation and assistance to be at Discovery Labs' cost and expense. Discovery Labs shall compensate DSM for its assistance at DSM's then-current market rates. Unless otherwise agreed, DSM shall not be required to provide assistance as provided herein longer than [***] following the date of termination or expiration of this Agreement.

13. Intellectual Property

(A) Definitions

"Discovery Labs' Method of Manufacture" constitutes valuable confidential proprietary information, patents, trade secrets and know-how of Discovery Labs and shall mean technology related to manufacture of pulmonary surfactants including but not limited to KL_4-based pulmonary surfactants such as, for example, Product.

"Discovery Labs' Patents" shall mean all patents owned by Discovery Labs or to which Discovery Labs otherwise has rights that claim or are directed to any Discovery Labs' Intellectual Property.

"Discovery Labs' Technology" shall mean (a) Discovery Labs' proprietary pulmonary surfactant technology (including without limitation the technologies, formulations, processes, equipment, materials and know how relating to the manufacture and use of pulmonary surfactants for treatment of respiratory conditions), and (b) all Intellectual Property owned by or licensed to Discovery Labs relating to such pulmonary surfactant technology, including, without limitation, the Discovery Labs' Patents, information related to KL_4 (sinapultide) and KL_4 surfactants (e.g., lucinactant, (SURFAXIN®), lyophilized lucinactant (SURFAXIN LS™) and lucinactant for inhalation (AEROSURF®)) and/or (c) method of making any of the foregoing, including Discovery Labs' Method of Manufacture, and/or method of using any of the foregoing, all rights licensed or acquired through third parties, including the capillary aerosol-generating technology rights that Discovery Labs is developing in connection with its aerosolized lucinactant.

"**Discovery Labs' Technology Package**" shall mean the technical information supplied by or on behalf of Discovery Labs to DSM to enable DSM to carry out its obligations hereunder, including technical expertise specific to the Product and to the manufacture of the Product. Items which may be included in Discovery Labs' Technology Package include, but are not limited to (i) Discovery Labs' Method of Manufacture, (ii) Discovery Labs' production records, (iii) Specifications for Product, APIs, other raw material and manufacturing components, intermediate Product, and storage conditions, (iv) analytical and microbiological method validation reports, (v) analytical method transfer protocols, and (vi) filter validation reports as supplied by Discovery Labs.

"**Intellectual Property**" shall mean patents, copyrights, trademarks, trade names, trade secrets, know-how, service marks, licenses and other intellectual property rights of a Party.

"**Invention**" means any new or improved apparatus, process, information, product, invention, discovery, idea, suggestion, material, data, equipment, design, circuit component, drawing, tooling, prototype, report, computer software, documentation or other Intellectual Property or know-how (whether or not patentable) discovered, produced, conceived, created or reduced to practice by either or both Parties (or their affiliates).

(B) Ownership

(i) Discovery Labs' Intellectual Property. Discovery Labs shall own (a) all Intellectual Property owned or controlled by Discovery Labs relating to Discovery Labs' Technology that was existing or conceived prior to the Effective Date or is developed by Discovery Labs outside of the performance of this Agreement, (b) all Intellectual Property relating to Discovery Labs' Technology developed by Discovery Labs outside of the performance of this Agreement or exercise of the license granted hereunder or to which Discovery Labs otherwise obtains rights from a third party, and (c) all Inventions conceived, created and reduced to practice solely by or on behalf of Discovery Labs in the course of the performance of this Agreement or exercise of the license granted hereunder; and (d) except to the extent covered by Paragraph 13(B)(ii)(c), all Inventions conceived, created and reduced to practice jointly by or on behalf of the Parties in the course of the performance of this Agreement or exercise of the license granted hereunder (collectively "Discovery Labs' Intellectual Property").

(ii) DSM Intellectual Property. DSM shall own (a) all Intellectual Property owned or controlled by DSM that was existing or conceived prior to the Effective Date, and (b) all Intellectual Property developed by DSM outside of the performance of this Agreement or to which DSM otherwise obtains rights from a third party (collectively "DSM Intellectual Property"); and (c) all Inventions consisting of improvements to the DSM Intellectual Property described in Paragraph 13(B)(ii)(a) to the extent severable from the Discovery Labs' Intellectual Property described in Paragraphs 13(B)(i)(a) and (b).

(iii) With regard to any Invention described in Paragraph 13(B)(ii)(c) above, that is derived in connection with the Services, DSM shall not use such Invention in connection with its manufacture of products other than the Product (in whatever form) that directly or indirectly competes or may compete with the utilization of KL_4-based pulmonary surfactants as a drug or as a carrier. Discovery Labs shall have a non-exclusive, worldwide, royalty free, perpetual license to use such Invention in connection with its manufacture of the Product (in whatever form and/or regard to Discovery Labs' Technology).

(C) Disclosure, Assignment, License and Exploitation.

(i) Disclosure. Each Party shall cause all personnel conducting work or exercising rights on its behalf under the Agreement to, promptly disclose to the other Party all Intellectual Property in which the other Party has an ownership interest pursuant to Section 13(B), and to assign any and all right, title and interest in all such Inventions and Intellectual Property in accordance with this Agreement. Each Party shall maintain records in sufficient detail and in good scientific manner appropriate for patent prosecution purposes to properly reflect all work done and results achieved in conducting its work hereunder, and shall respond to reasonable requests of the other Party for information regarding Intellectual Property in which the other Party has an ownership interest.

(ii) Assignment and License. In the event DSM conceives, creates or reduces to practice any Discovery Labs' Intellectual Property, DSM shall promptly notify Discovery Labs and DSM shall assign all right, title and interest in and to such Discovery Labs' Intellectual Property to Discovery Labs. In the event Discovery Labs conceives, creates or reduces to practice any DSM Intellectual Property, Discovery Labs shall promptly notify DSM and Discovery Labs shall assign all right, title and interest in and to such DSM Intellectual Property to DSM.

(iii) Discovery Labs hereby grants DSM a nonexclusive, royalty-free license during the term of this Agreement to use Discovery Labs' Technology Package, Discovery Labs' Method of Manufacture and Discovery Labs' Intellectual Property rights solely in the performance of DSM's obligations under this Agreement.

(iv) Except as expressly stated in this Agreement, no Intellectual Property rights of any kind or nature are conveyed by this Agreement and except as set forth in this Section 13(C) and Section 13(B)(iii), neither Party shall have any right, title or interest in or to the other Party's Intellectual Property rights for any purpose whatsoever without such other Party's prior written consent. Upon termination of this Agreement for whatever reason, neither Party shall use or exploit in any manner whatsoever any Intellectual Property rights of the other Party.

14. Force Majeure. Neither Party shall be held liable or responsible for any loss or damages resulting from any delay in its performance due hereunder (other than the payment of funds due hereunder) caused by the occurrence of any condition beyond the reasonable control of the affected Party including, without limitation, Acts of God, strikes or other labor disputes, war, riot, earthquake, tornado, hurricane, fire, civil disorder, explosion, accident, flood, sabotage, lack of or inability to obtain adequate fuel, power, materials, labor, containers, transportation, supplies or equipment after commercially reasonable efforts to do so; compliance with governmental requests, laws, rules, regulations, orders or actions; inability despite good faith efforts to renew operating permits or licenses from local, state or federal governmental authorities; breakage or failure of machinery or apparatus; national defense requirements; or supplier strike, lockout or injunction. In the event either Party is delayed or rendered unable to perform due to Force Majeure, the affected Party shall give prompt notice of the conditions and the expected duration to the other Party promptly after the occurrence of the cause relied upon, and upon the giving of such notice the obligations of the Party giving the notice will be suspended during the continuance of the Force Majeure.

15. Dispute Resolution. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement which relates to either Party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either Party may, by notice to the other Party, have such dispute referred to their senior officers as may be designated by each Party for attempted resolution by good faith negotiations within [***] after such notice is received. In the event the designated officers are not able to resolve such dispute within such [***] period, or such other period of time as the Parties may mutually agree in writing, the Parties shall be obligated to submit the dispute to binding arbitration in accordance with the rules of the American Arbitration Association ("AAA") for commercial arbitration, utilizing three (3) arbitrators mutually agreeable to the Parties. If the Parties are unable to reach agreement as to one or more of the arbitrators, the arbitrators shall be chosen in accordance with the AAA commercial arbitration rules. The arbitrators shall present a detailed written statement of their findings; and the Parties shall be bound thereby. The arbitration proceedings and any documents or other information disclosed in connection therewith shall be subject to the requirements of confidentiality as set forth in Section 5.

16. Insurance. Each Party shall at all times maintain all necessary insurance coverage with sound and reputable independent insurers at commercially reasonable levels of coverage or shall be self insured having regard to the nature, type, scope and size of the business it conducts and all its respective activities and obligations under this Agreement. General liability coverage in the amount of at least [***] hereunder shall be maintained by each Party. Each Party shall, upon reasonable request of the other Party, produce satisfactory evidence that all insurance premiums have been paid and kept up to date and are kept in accordance with local insurance laws or regulations from time to time in force, or shall furnish appropriate certificates of insurance showing proof of coverage. The insurance coverage may be provided through a combination of primary, excess/umbrella or self-insured retention, and shall not serve to operate as a limitation on the recovery of any claim. Each Party shall include the other Party as an additional insured on its policies of insurance, as the other Party's interests may be affected pursuant to this Agreement.

17. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without reference to principles of conflicts of law, and the arbitration proceedings as provided in Section 15 shall take place in New York unless the Parties agree on an alternate location.

18. Legal Compliance. Each Party shall comply in all material respects with all federal and state laws and regulations applicable to the conduct of its business pursuant to this Agreement, including, but not limited to, the United States Federal Food, Drug and Cosmetic Act, as amended.

19. Authorization.

(A) DSM hereby represents and warrants to Discovery Labs that all corporate action on the part of DSM and its officers and directors necessary for the authorization, execution and delivery of this Agreement and the performance of all obligations of DSM hereunder has been taken.

(B) Discovery Labs hereby represents and warrants to DSM that all requisite action on the part of Discovery Labs and its officers and directors necessary for the authorization, execution and delivery of this Agreement and the performance of all obligations of Discovery Labs hereunder has been taken.

20. The Parties shall enter into a Quality Agreement in form reasonably acceptable to both Parties (the "Quality Agreement") that further details the quality assurance obligations and responsibilities of the Parties with respect to the Product. Notwithstanding anything to the contrary in this Agreement or in any other document or agreement, in the event of a conflict between this Agreement and the Quality Agreement, the Quality Agreement shall govern and control with respect to quality-related matters; and this Agreement shall govern and control with respect to all other matters.

21. Entire Agreement; Prior Agreements. This Agreement and attachments contain the entire understanding between the Parties with respect to the subject matter hereof, and may be modified, only by a written instrument duly executed by each Party's authorized representative. This Agreement shall supersede any prior agreements in respect of the services to be performed hereunder, (i) except for the Mutual Confidential Disclosure Agreement referred to in Section 5, and (ii) except that [***].

22. Independent Contractor. Discovery Labs will not have the right to direct or control the activities of DSM in performing the Services provided herein. DSM shall perform the Services hereunder only as an independent contractor; and nothing herein shall be construed to be inconsistent with the status of independent contractor. Neither Party shall be an agent of the other Party; nor shall either Party's employees be employees of the other Party.

23. Assignment; Subcontractors. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement: (a) in connection with the transfer or sale of all or substantially all of the assets of such Party or the line of business of which this Agreement forms a part; (b) in the event of the merger or consolidation of a Party hereto with another company; or (c) to any Affiliate of the assigning Party. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either Party of the responsibility for the performance of any obligation which accrued prior to the effective date of such assignment. At its option, DSM may use subcontractors to perform parts of this Agreement, provided such subcontractors are bound by a confidentiality agreement with DSM and meet such other quality standards as may be imposed on DSM under this Agreement.

24. Any and all exhibits, schedules and attachments (including SOWs) referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

25. Notices. All notices and other communications required or permitted to be given under this Agreement shall be in writing and shall be delivered personally or sent by (a) registered or certified mail, return receipt requested, (b) a nationally-recognized courier service guaranteeing next-day delivery, charges prepaid or (c) facsimile (with the original promptly sent by any of the foregoing manners), and shall be deemed to have been given upon mailing or upon transmission by facsimile, as the case may be. Any such notices shall be addressed to the receiving Party at such Party's address set forth below, or at such other address as may from time to time be furnished by similar notice by either Party:

If to DSM: DSM Pharmaceuticals, Inc.
[***]
[***]
[***]
[***]

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

26. Waiver. Neither Party's waiver of any breach or failure to enforce any of the terms and conditions of this Agreement, at any time, shall in any way affect, limit or waive such Party's right thereafter to enforce and compel strict compliance with every term and condition of this Agreement.

27. Severability. Each Party hereby expressly agrees that it has no intention to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries; that if any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or either Party hereto, in a final unappealed order, to be in violation of any such provisions in any country or community or association of countries, such words, sentences, paragraphs, clauses or combination shall be inoperative in such country or community or association of countries and the remainder of this Agreement shall remain binding upon the Parties, so long as enforcement of the remainder does not violate the Parties' overall intentions in this transaction.

IN WITNESS WHEREOF, the Parties have signed this Master Services Agreement by and through their authorized representatives, effective as of the date first set forth above.

DSM Pharmaceuticals, Inc.

By: _____
[***] _____
[***] _____

Discovery Laboratories, Inc.

By: _____
Name: _____
Title: _____

ADDENDUM I

[Form of] Equipment Purchase Order Addendum

Addendum to Purchase Order between Discovery Laboratories, Inc. ("Discovery Labs") and
DSM Pharmaceuticals, Inc. ("DSM").

Each of Discovery Labs and DSM agree that:

· The purchase of all equipment, and related accessories (the "Equipment"), shall be specified in writing in sufficient detail and must be authorized in writing in advance by Discovery Labs.

· The Equipment purchased on behalf of Discovery Labs will be shipped directly to the DSM facility at _____.

· The Equipment shall be used solely in rendering the Services being provided to Discovery Labs by DSM.

· Discovery Labs shall retain ownership of the Equipment, which is being delivered to DSM in connection with the Purchase Order, dated [_____], between the parties to which this Addendum is appended and made a part. DSM agrees that it will take no action against the ownership interests of Discovery Labs and will not represent to any third party that it owns or has any interest in the Equipment. Further, principally in cases in which Discovery Labs avails itself of third-party capital financing where such party's lien and security interests require it, the Equipment shall be clearly labeled as being the possession of Discovery Labs and DSM agrees not to remove, modify or deface the label.

· Upon receipt of the Equipment, DSM shall inspect the Equipment and inform Discovery Labs of any damage to the Equipment and shall cooperate with Discovery Labs if any claim against the manufacturer, distributor and shipper should become necessary. To the extent practicable, DSM shall retain the original packaging materials and crate.

· DSM shall maintain the Equipment in accordance with manufacturer specifications. DSM will ensure that any manufacturer and/or dealer warranties will be assigned or assignable to Discovery Labs. DSM shall not remove the Equipment from the destination designated above without the prior written agreement of Discovery Labs.

· DSM shall safeguard the Equipment with at least the same level of care as DSM uses in safeguarding its own equipment of a similar nature. DSM shall maintain adequate insurance, in coverage and amount, with respect to the Equipment.

· DSM shall be responsible for routine maintenance and servicing of such Equipment so long as such Equipment remains at DSM's facility, using the same care that it uses with its own equipment. Discovery Labs shall be responsible for the cost of non-routine maintenance and servicing of such Equipment (such as major repairs and parts replacement). DSM shall notify Discovery Labs prior to the performance of any non-routine maintenance or servicing, and Discovery Labs shall directly pay or promptly reimburse DSM (as the case may be) for any such maintenance or servicing costs that Discovery Labs has authorized to be incurred and for which it is responsible.

· Upon the request of Discovery Labs, DSM shall return the Equipment to Discovery Labs, at Discovery Labs' cost, in good working condition and, to the extent practicable, in the original packing materials and crate.

DSM Pharmaceuticals, Inc.

By: _____
Name: _____
Title: _____

Discovery Laboratories, Inc.

By: _____
Name: _____
Title: _____

Exhibit 31.1

CERTIFICATIONS

I, John G. Cooper, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2013

/s/ John G. Cooper
John G. Cooper
President and Chief Executive and Chief Financial Officer
(Principal Executive and Financial Officer)

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, the undersigned officer 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, 2013 (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 12, 2013

/s/ John G. Cooper
John G. Cooper
President and Chief Executive Officer and Chief Financial Officer
(Principal Executive and 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.