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 June 30, 2013

or

o **QUARTERLY 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 July 31, 2013, 54,788,094 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 are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including 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:

- The risks that the United States (U.S.) Food and Drug Administration (FDA) may not review our recent response to its correspondence addressing our earlier submission concerning our improved analytical chemistry method and updated SURFAXIN drug product specifications within four months of our June 7, 2013 submission date, as anticipated, or may not agree with our submission, which could prevent our proceeding with the commercial introduction of SURFAXIN as planned, if ever; and that, if the delay in commercial availability of SURFAXIN extends beyond December 31, 2013, we may be unable to access $20 million under the Deerfield Facility, which could have a material adverse effect on our ability to fund our operations;

- the risks that the delay in anticipated commercial availability of SURFAXIN until the fourth quarter of 2013 could adversely impact our plans and our ability to meet our objectives, and that any further delay could have a material adverse effect on our business, operations and financial condition;

- the risk that, even if the FDA agrees with our recent response to its correspondence concerning our improved analytical chemistry method and updated SURFAXIN drug product specifications, and we are able to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013 and thereby secure an additional $20 million under the Deerfield Facility, we nevertheless 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, including our planned clinical programs, 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. Moreover, we have pledged substantially all of our assets to secure our obligations under the Deerfield Facility, which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investments;

- the risk that, although we plan to continue to slow the pace of certain investments that we otherwise would make during this period, our plan to maintain our commercial and medical affairs capabilities and continue to invest in the AEROSURF® development program will limit our ability to significantly reduce our cash outflows;

- the risk that, if we fail to successfully commercialize SURFAXIN and AFECTAIR as planned, or if SURFAXIN and AFECTAIR do not gain market acceptance for any reason and 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 risk that we may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us in markets outside the U.S. with the development of our KL4 surfactant pipeline products, beginning with AEROSURF (our combination drug-device product based on our aerosolized KL4 surfactant and our CAG technology that we are developing to address RDS in premature infants), and including the development of our lyophilized KL4 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 SURFAXIN LS™, our lyophilized dosage form of SURFAXIN;

- risks relating to the ability of our sales and marketing organization to effectively market SURFAXIN and AFECTAIR in the U.S., and our other product candidates, if approved, 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;

- risks relating to our contract manufacturer organizations' (CMOs) ability to manufacture our KL4 surfactant, 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, AFECTAIR aerosol-conducting airway connectors, 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, as well as our research and development activities for our other product candidates;

- risks relating to the transfer of our manufacturing technology to CMOs and assemblers; 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 on March 15, 2013, 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 advanced 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)

	June 30, 2013 (Unaudited)	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 31,253	$ 26,892
Inventory	36	195
Prepaid expenses and other current assets	618	719
Total Current Assets	31,907	27,806
Property and equipment, net	1,493	1,737
Restricted cash	400	400
Other Assets	107	–
Total Assets	$ 33,907	$ 29,943
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,919	$ 1,166
Accrued expenses	4,739	4,159
Common stock warrant liability	3,619	6,305
Equipment loans and capitalized leases, current portion	71	69
Total Current Liabilities	10,348	11,699
Long-term debt, net of discount of $3,799 at June 30, 2013 and $0 at December 31, 2012	6,201	–
Equipment loans and capitalized leases, non-current portion	109	148
Other liabilities	433	443
Total Liabilities	17,091	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 June 30, 2013, 100,000,000 shares authorized at December 31, 2012; 54,808,986 and 43,673,636 shares issued, 54,788,094 and 43,652,744 shares outstanding at June 30, 2013 and December 31, 2012, respectively	55	44
Additional paid-in capital	475,813	455,398
Accumulated deficit	(455,998)	(434,735)
Treasury stock (at cost); 20,892 shares	(3,054)	(3,054)
Total Stockholders' Equity	16,816	17,653
Total Liabilities & Stockholders' Equity	$ 33,907	$ 29,943

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Grant revenue	$ 182	$ –	$ 254	$ –
Expenses:				
Research and development	6,863	5,206	15,335	9,739
Selling, general and administrative	4,129	3,610	8,349	5,657
Total expenses	10,992	8,816	23,684	15,396
Operating loss	(10,810)	(8,816)	(23,430)	(15,396)
Change in fair value of common stock warrant liability	2,525	1,680	2,686	(1,754)
Interest expense	(343)	(4)	(520)	(8)
Interest and other income, net	1	2	1	4
Net loss	$ (8,627)	$ (7,138)	$ (21,263)	$ (17,154)
Net loss per common share –				
Basic	$ (0.18)	$ (0.16)	$ (0.46)	$ (0.49)
Diluted	$ (0.22)	$ (0.16)	$ (0.50)	$ (0.49)
Weighted average number of common shares outstanding				
Basic	49,135	43,369	46,411	35,325
Diluted	49,866	43,369	47,773	35,325

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

(in thousands)

	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
Cash flows from operating activities:		
Net loss	$ (21,263)	$ (17,154)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	364	576
Stock-based compensation and 401(k) match	1,489	1,109
Fair value adjustment of common stock warrants	(2,686)	1,754
Amortization of discount on long-term debt	177	–
Changes in:		
Inventory	159	(105)
Prepaid expenses and other current assets	101	9
Accounts payable	753	224
Accrued expenses	580	(380)
Other assets	(107)	–
Other liabilities	(10)	(3)
Net cash used in operating activities	(20,443)	(13,970)
Cash flows from investing activities:		
Purchase of property and equipment	(120)	(518)
Net cash used in investing activities	(120)	(518)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	15,110	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	(37)	(39)
Net cash provided by financing activities	24,924	50,307
Net increase in cash and cash equivalents	4,361	35,819
Cash and cash equivalents – beginning of period	26,892	10,189
Cash and cash equivalents – end of period	$ 31,253	$ 46,008
Supplementary disclosure of cash flows information:		
Interest paid	$ 336	$ 7

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. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs have the potential to greatly improve the management of RDS and, over time, to become a new standard of care for premature infants with RDS.

The United States (U.S.) Food and Drug Administration (FDA) granted us regulatory approval for SURFAXIN® (lucinactant) for the prevention of RDS in premature infants at high risk for RDS in March 2012. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. In the third quarter of 2012, our plans for the commercial introduction of SURFAXIN were delayed when, during a routine review of our processes related to analytical testing and quality control of SURFAXIN drug product, we determined that one analytical chemistry method used to assess SURFAXIN drug product required improvement and that an update to SURFAXIN product specifications was needed. We communicated with the FDA, improved and revalidated the analytical chemistry method, and submitted updated product specifications to the FDA. In April 2013, the FDA requested information and provided recommendations intended to clarify certain aspects of our revalidated analytical chemistry method and updated product specifications. On June 7, 2013, we submitted our response to the FDA. We expect that the FDA may take up to four months to review and respond to our submission. If we are successful and the FDA agrees with our submission within the anticipated time, we expect to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013. There can be no assurance, however, that the FDA will respond within the anticipated time or agree with our proposed updated product specifications. Any extended delay in the commercial availability of SURFAXIN could have a material adverse effect on our ability to fund our operations and our development programs.

AEROSURF® is a combination drug-device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). We are developing AEROSURF to address RDS in premature infants. Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that frequently result in serious respiratory conditions and complications. Neonatologists generally attempt to provide respiratory support to neonates using less invasive means, such as nasal continuous positive airway pressure (nCPAP), and consequently will not treat infants who could benefit from surfactant therapy unless they determine that the potential benefits of surfactant therapy outweigh the risks associated with endotracheal intubation and mechanical ventilation. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy to premature infants supported with nCPAP. For this reason, we believe that AEROSURF, if approved, potentially 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 KL_4 surfactant that is stored as a powder and resuspended to liquid form prior to use 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 continuing to develop the manufacturing process for our lyophilized KL_4 surfactant with a contract manufacturing organization (CMO) that has expertise in lyophilized products, and we expect that it will manufacture lyophilized KL_4 surfactant for use in our preclinical and clinical development activities, including potentially in our planned AEROSURF phase 2 clinical program, which is expected to initiate in the fourth quarter 2013. 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.

Our objectives for 2013 include initiating the commercial introduction of SURFAXIN and advancing the AEROSURF development program to Phase 2 clinical trials. If we are able to accomplish these goals, we believe we will be able to apply the knowledge and experience gained to develop a pipeline of innovative products based on our technologies intended to address other critical care respiratory conditions in the NICU, PICU and intensive care units (ICUs).

AFECTAIR® aerosol-conducting airway connector is our novel disposable device intended to simplify the delivery of our aerosolized KL_4 surfactant, and other aerosolized medications and inhaled therapies, to infants in neonatal or pediatric intensive care units (NICUs and PICUs, respectively) who require ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. In February 2012, we registered our AFECTAIR device in the U.S. as a Class I, exempt medical device. We currently are conducting a national user experience program in select institutions across the United States.

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 primarily will be responsible for the commercial introduction of SURFAXIN and the AFECTAIR device for infants. In the future, 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, as well as other potential products that could have benefit in the NICU/PICU.

An important priority for us is to secure strategic and financial resources to support our operations and advance our KL_4 surfactant and aerosol device development programs and the commercial introduction of our approved RDS products. *See*, Note 2 – "Liquidity Risks and Management's Plans." For our development programs, 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 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. In 2013, we are focused on securing a significant strategic alliance predominantly focused on 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 June 30, 2013, we had cash and cash equivalents of $31.3 million, approximately $6.7 million of accounts payable and accrued expenses, and $10 million of long-term debt under the Deerfield Facility, which also provides for an additional advance of $20 million to be paid upon the first commercial sale of SURFAXIN drug product, provided that such sale occurs on or before December 31, 2013. *See*, Note 6 – "Long-Term Debt – Loan Facility with Deerfield." Since the commercial availability of SURFAXIN drug product has been delayed until potentially the fourth quarter of 2013, the second Deerfield advance also has been delayed. To manage our resources during this delay, we reviewed and assessed our planned activities. We decided to maintain investments in our commercial and medical affairs capabilities and in our AEROSURF development program, in particular, the activities needed to initiate our planned AEROSURF phase 2 clinical program in the fourth quarter of 2013. To conserve cash resources, we implemented a plan to pace certain other investments in our operations and commercial and development programs through the fourth quarter of 2013. Before any financings, including under our ATM Program (see, Note 4 - "Stockholders' Equity - At-the-Market Program (ATM Program)") and before the expected $20 million advance under the Deerfield Facility, we anticipate that we have sufficient cash available to support our operations and debt service obligations into the first quarter of 2014.

Even if we succeed and SURFAXIN drug product and the AFECTAIR device are introduced commercially as planned and we secure the Deerfield additional $20 million advance, 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. Such infusions of capital could come from potential strategic alliances and collaboration arrangements, debt financings, public offerings and other similar transactions. Since the $20 million advance under the Deerfield Facility is payable only if the first commercial sale of SURFAXIN drug product occurs on or before December 31, 2013, our access to funds under the Deerfield Facility could expire if we fail to complete the first commercial sale of SURFAXIN drug product in 2013. Given the time required to secure formulary acceptance of SURFAXIN at our target hospitals and acceptance of our new device, 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.

The accompanying interim unaudited financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As a result of our year-end cash position, the audit opinion we received from our independent auditors for the year ended December 31, 2012 contains a notation related to our ability to continue as a going concern. Whether we can continue as a going concern is dependent upon our ability to raise additional capital, fund our commercial activities and development programs, and meet our obligations on a timely basis. If we are unable to secure sufficient additional capital, through potential strategic partnerships and collaborative arrangements, debt and/ or equity financings and other similar transactions, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit our commercial activities and development programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to secure the necessary capital, we may be forced to curtail all activities and, ultimately, cease operations. Even if we are able to secure additional capital, such transactions may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our June 30, 2013 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

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 expect that we may receive $20 million additional capital under our Deerfield Facility. Through our ATM Program, we have the ability to sell up to $25 million of common stock at such times and in such amounts that we deem appropriate. However, we may not gain access to the funds available under the Deerfield Facility and the ATM Program can be cancelled at any time by either party. We also plan to consider other public and private equity offerings as well as financing transactions, such as secured equipment financing facilities or other similar transactions.

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 initiation of the planned phase 2 clinical program in the fourth quarter of 2013; 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 SURFAXIN LS, in markets outside the U.S. We believe that our ability to enter into a significant strategic alliance will likely improve if we remain on track to initiate both the commercial sale of SURFAXIN and our AEROSURF phase 2 clinical program in the fourth quarter of 2013. 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.

As of June 30, 2013, 150 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 76.3 million shares of common stock were available for issuance and not otherwise reserved.

On May 15, 2013, we completed a public offering of 9.5 million shares of common stock, at a price of $1.50 per share resulting in net proceeds to us (after underwriter fees and anticipated expenses) of approximately $13.2 million. 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.

As of June 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 (Deerfield Warrants) in connection with the first advance under the Deerfield Facility. 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 warrants. In addition, 4.9 million are February 2011 five-year warrants, which 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 issued at an exercise price of $3.20 per share, which was thereafter adjusted downward, first to $2.80 per share following the public offering in March 2012 and then to $1.50 per share following the 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.

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 six months ended June 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 the delay in commercial availability of SURFAXIN drug product, previously capitalized raw material costs of $195,072 were charged to research & development expense in the first quarter of 2013, as these raw materials are no longer expected to be used for commercial production. SURFAXIN raw material purchases will be charged to research & development expense until the FDA confirms our updated product specifications and we are able to proceed with the commercial introduction of SURFAXIN, anticipated in the fourth quarter of 2013. Inventory costs for our AFECTAIR device consist primarily of third-party manufacturing fees, freight, and indirect personnel overhead costs. As of June 30, 2013, inventories consisted of $36,200 of AFECTAIR devices available for commercial sale.

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 six months ended June 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, the 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 three and six months ended June 30, 2013, the effect of the adjustments for warrants issued in February 2011 were dilutive. For the three and six months ended June 30, 2012, the effect of the adjustments for all warrants classified as derivative liabilities were 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 June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Numerator:				
Net loss as reported	$ (8,627)	$ (7,138)	$ (21,263)	$ (17,154)
Less: income from change in fair value of warrant liability	(2,494)	–	(2,584)	–
Numerator for diluted net loss per common share	$ (11,121)	$ (7,138)	$ (23,847)	$ (17,154)
Denominator:				
Basic weighted average common shares outstanding	49,135	43,369	46,411	35,325
Dilutive common shares from assumed warrant exercises	731	–	1,362	–
Diluted weighted average common shares outstanding	49,866	43,369	47,773	35,325

As of June 30, 2013 and 2012, 10.8 million and 11.8 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 six months ended June 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 60 days after the date of the prospectus supplement ending on July 9, 2013.

At-the-Market Program (ATM Program)

On February 11, 2013, we entered into an At-the-Market Equity Offering Sales Agreement (ATM Program) with Stifel pursuant to 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 common stock at any time during the term of the ATM Program. If we issue a sale notice to Stifel, we may designate the minimum price per share at which our common stock may be sold and the maximum number of shares that Stifel is directed to sell during any selling period. As a result, prices are expected to vary as between purchasers and during the term of the offering. Stifel may sell shares by any method deemed to be an "at-the-market" equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, which may include ordinary brokers' transactions on The Nasdaq Capital Market, or otherwise at market prices prevailing at the time of sale or prices related to such prevailing market prices, or as otherwise agreed by Stifel and us. The shares to be offered under the ATM Program are registered under our universal shelf registration statement on Form S-3 that we filed with the SEC on June 8, 2011 (2011 Universal Shelf).

The ATM Program will terminate upon the earliest of: (1) the sale of all shares of common stock issuable thereunder, (2) February 11, 2016 or (3) other termination in accordance with the terms of the related agreement. Either party may terminate the ATM Program at any time upon written notification to the other party in accordance with the related agreement.

We have agreed to pay Stifel a commission equal to 3.0% of the gross sales price of shares sold pursuant to the ATM Program. With the exception of expenses related to the shares of common stock, Stifel will be responsible for all of its own costs and expenses incurred in connection with the ATM Program.

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. We were not obligated to issue any shares under the CEFF. Our ability to access the CEFF was subject to certain covenants and conditions, including stock price and volume limitations. *See also*, Note 10 – Stockholders' Equity – Registered Public Offerings – Committed Equity Financing Facility (CEFF), to the consolidated financial statements in our in our 2012 Form 10-K, for a detailed description of our CEFF.

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 June 30, 2013 and December 31, 2012:

	Fair Value	Fair value measurement using		
	June 30, 2013	Level 1	Level 2	Level 3
Assets:				
Money Market	$ 25,877	$ 25,877	$ –	$ –
Certificate of Deposit	400	400	–	–
Total Assets	$ 26,277	$ 26,277	$ –	$ –
Liabilities:				
Common stock warrant liability	$ 3,619	$ –	$ –	$ 3,619

	Fair Value	Fair value measurement using		
	December 31, 2012	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 six months ended June 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	(2,686)
Balance at June 30, 2013	$ 3,619

(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	1,754
Balance at June 30, 2012	$ 8,614

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	June 30, 2013	December 31, 2012
Historical Volatility	61% - 74%	56% -80%
Expected Term (in years)	0.9 – 2.6	1.4 – 3.2
Risk-free interest rate	0.14% - 0.55%	0.16% - 0.36%

Fair Value of Long-Term Debt

As of June 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 the Deerfield Facility with 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), provided that the Milestone Date occurs on or before December 31, 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 (x) 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 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 may receive a transaction fee equal to 1.5% of any 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 the Deerfield Warrants to purchase approximately 2.3 million shares of our common stock at an exercise price of $2.81. If the Milestone Date, as defined in the facility agreement, occurs, upon disbursement of the additional $20 million loan under the facility agreement, 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 of common stock (together with the Deerfield Warrants, the "Warrants"). There can be no assurance that the Milestone Date will occur. The number of shares of common stock into which a Warrant is exercisable and the exercise price of any Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock.

Each Warrant will expire on the sixth anniversary of the facility agreement and contains certain limitations that generally prevent the holder from acquiring shares upon exercise of a 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 Warrant may exercise all or a portion of the Warrant either for cash or on a cashless basis. In connection with a Major Transaction, as defined in the 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 Warrant or that portion of the Warrant for cash in an amount equal to the Black-Scholes value (as defined in the Warrant) of the Warrant or that portion of the 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 Warrant and receive therefor that number of shares of Common Stock that equals the Black-Scholes value of the Warrant or that portion of the Warrant exercised. Prior to the holder exercising the Warrant for shares in such transactions, the Company may elect to terminate the Warrant or that portion of the Warrant and pay the holder cash in an amount equal to the Black-Scholes value of the 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 June 30, 2013 consists solely of amounts due under the Deerfield Facility as follows:

Note Payable	$ 10,000
Unamortized discount	(3,799)
Long-term debt, net of discount	$ 6,201

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

(in thousands)	**Three Months Ended June 30,**		**Six Months Ended June 30,**	
	2013	**2012**	**2013**	**2012**
Cash interest expense	$ 218	$ –	$ 331	$ –
Non-cash amortization of debt discounts	118	–	177	–
Amortization of debt costs	5	–	8	–
Total Deerfield Facility interest expenses	$ 341	$ –	$ 516	$ –

Cash interest expense represents interest of 8.75% on the outstanding principal amount for the period, paid 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 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 June 30, 2013 are as follows:

Issuance Date	Number of Warrant Shares	Exercise Price	Warrant Expiration Date	Fair Value of Warrants (in thousands)	
				Issuance Date	June 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	3
2/22/2011	4,948,750	1.50	2/22/2016	8,004	3,616

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	4.7 years	4.8 years
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:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Research & Development	$ 200	$ 118	$ 341	$ 238
Selling, General & Administrative	407	288	622	566
Total	$ 607	$ 406	$ 963	$ 804

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 Securities and Exchange Commission (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. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs have the potential to greatly improve the management of RDS and, over time, to become a new standard of care for premature infants with RDS.

The United States (U.S.) Food and Drug Administration (FDA) granted us regulatory approval for SURFAXIN® (lucinactant) for the prevention of RDS in premature infants at high risk for RDS in March 2012. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. In the third quarter of 2012, our plans for the commercial introduction of SURFAXIN were delayed when, during a routine review of our processes related to analytical testing and quality control of SURFAXIN drug product, we determined that one analytical chemistry method used to assess SURFAXIN drug product required improvement and that an update to SURFAXIN product specifications was needed. We communicated with the FDA, improved and revalidated the analytical chemistry method, and submitted updated product specifications to the FDA. In April 2013, the FDA requested information and provided recommendations intended to clarify certain aspects of our revalidated analytical chemistry method and updated product specifications. On June 7, 2013, we submitted our response to the FDA. We expect that the FDA may take up to four months to review and respond to our submission. If we are successful and the FDA agrees with our submission within the anticipated time, we expect to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013. There can be no assurance, however, that the FDA will respond within the anticipated time or agree with our proposed updated product specifications. Any extended delay in the commercial availability of SURFAXIN could have a material adverse effect on our ability to fund our operations and our development programs.

AEROSURF® is a combination drug-device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). We are developing AEROSURF to address RDS in premature infants. Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that frequently result in serious respiratory conditions and complications. Neonatologists generally attempt to provide respiratory support to neonates using less invasive means, such as nasal continuous positive airway pressure (nCPAP), and consequently will not treat infants who could benefit from surfactant therapy unless they determine that the potential benefits of surfactant therapy outweigh the risks associated with endotracheal intubation and mechanical ventilation. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy to premature infants supported with nCPAP. For this reason, we believe that AEROSURF, if approved, potentially 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 that is stored as a powder and resuspended to liquid form prior to use 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 continuing to develop the manufacturing process for our lyophilized KL4 surfactant with a contract manufacturing organization (CMO) that has expertise in lyophilized products, and we expect that it will manufacture lyophilized KL4 surfactant for use in our preclinical and clinical development activities, including potentially in our planned AEROSURF phase 2 clinical program, which is expected to initiate in the fourth quarter 2013. 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.

Our objectives for 2013 include initiating the commercial introduction of SURFAXIN and advancing the AEROSURF development program to Phase 2 clinical trials. If we are able to accomplish these goals, we believe we will be able to apply the knowledge and experience gained to develop a pipeline of innovative products based on our technologies intended to address other critical care respiratory conditions in the NICU, PICU and intensive care units (ICUs).

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 neonatal or pediatric intensive care units (NICUs and PICUs, respectively) who require ventilatory support by introducing the aerosolized medication directly at the patient interface and minimizing the number of connections in the ventilator circuit. In February 2012, we registered our AFECTAIR device in the U.S. as a Class I, exempt medical device. We currently are conducting a national user experience program in select institutions across the United States.

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 primarily will be responsible for the commercial introduction of SURFAXIN and the AFECTAIR device for infants. In the future, 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, as well as other potential products that could have benefit in the NICU/PICU.

An important priority for us is to secure strategic and financial resources to support our operations and advance our KL4 surfactant and aerosol device development programs and the commercial introduction of our approved RDS products. *See*, "– Liquidity and Capital Resources." For our development programs, 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 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. In 2013, we are focused on securing a significant strategic alliance predominantly focused on 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 intended to clarify certain aspects of the updated product specifications and the revalidated analytical chemistry method; recommendations regarding how the product specifications should be documented and notated; a specific recommendation for the upper limit of a single product specification, which we can readily accept; a request for two existing and readily available documents related to the improved analytical chemistry method; and a request for supporting data using the improved and revalidated analytical chemistry method that is being generated from recent SURFAXIN batches. We completed the required work and submitted our response to the FDA on June 7, 2013. We anticipate that the FDA may take up to four months from the date of submission to review and respond to our response. If we are successful and the FDA agrees with our submission within the anticipated time, we expect to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013.

- AEROSURF

We remain on track to initiate the first part of our phase 2 clinical program in the fourth quarter of 2013. We continue to advance our CAG development program, and are working with Battelle Memorial Institute (Battelle) to prepare a clinic-ready device and manufacture a sufficient number of CAG devices for use in our planned AEROSURF phase 2 clinical trials. We have developed the CAG for use with either our liquid or lyophilized dosage forms of our KL4 surfactant product. We also are continuing development of our lyophilized KL4 surfactant and are finalizing a Master Services Agreement (MSA) with DSM Pharmaceuticals, Inc. (DSM), the CMO with whom we have been conducting a technology transfer of our lyophilized KL4 surfactant manufacturing process, although there can be no assurance that we will successfully enter into the MSA. The MSA is intended to support further development activities, including manufacture of our lyophilized KL4 surfactant drug product for use in preclinical and clinical activities, including our AEROSURF phase 2 clinical program. We are also collaborating with our AEROSURF steering committee, which consists of key thought leaders in neonatology, to finalize the design of our AEROSURF clinical program.

We remain on track to initiate the first part of our phase 2 clinical program in the fourth quarter of 2013. We continue to advance our CAG development program, and are working with Battelle Memorial Institute (Battelle) to prepare a clinic-ready device and manufacture a sufficient number of CAG devices for use in our planned AEROSURF phase 2 clinical trials. We have developed the CAG for use with either our liquid or lyophilized dosage forms of our KL4 surfactant product. We also are continuing development of our lyophilized KL4 surfactant and are finalizing a Master Services Agreement (MSA) with DSM Pharmaceuticals, Inc. (DSM), the CMO with whom we have been conducting a technology transfer of our lyophilized KL4 surfactant manufacturing process, although there can be no assurance that we will successfully enter into the MSA. The MSA is intended to support further development activities, including manufacture of our lyophilized KL4 surfactant drug product for use in preclinical and clinical activities, including our AEROSURF phase 2 clinical program. We are also collaborating with our AEROSURF steering committee, which consists of key thought leaders in neonatology, to finalize the design of our AEROSURF clinical program.

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 June 30, 2013 and 2012 was $8.6 million (or $0.18 basic net loss per share) and $7.1 million (or $0.16 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 $2.5 million and $1.7 million for 2013 and 2012, respectively.

The net loss for the six months ended June 30, 2013 and 2012 was $21.3 million (or $0.46 basic net loss per share) and $17.2 million (or $0.49 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 $2.7 million and non-cash expense of $1.8 million in 2013 and 2012, respectively.

The operating loss for the three months ended June 30, 2013 and 2012 was $10.8 million and $8.8 million, respectively. The increase in operating loss from 2012 to 2013 is primarily due to (i) a $1.7 million increase in investment in the AEROSURF development program, primarily to prepare the CAG for clinical use in anticipation of our AEROSURF phase 2 clinical trials, and advance the technology transfer of our lyophilized KL4 surfactant manufacturing process to our CMO, (ii) a $1.2 million increase in 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 (iii) partially offset by a $1.4 million reduction in costs associated with employee incentive compensation.

The operating loss for the six months ended June 30, 2013 and 2012 was $23.4 million and $15.4 million, respectively. The increase in operating loss from 2012 to 2013 is primarily due to (i) a $3.8 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 $3.5 million increase in investment in the AEROSURF development program, primarily to prepare the CAG for clinical use in anticipation of our AEROSURF phase 2 clinical trials, and advance the technology transfer of our lyophilized KL4 surfactant manufacturing process to our CMO, and (iii) a $1.1 million increase in purchases of raw materials to manufacture drug product for SURFAXIN and our AEROSURF development program.

Grant Revenue

For the three and six months ended June 30, 2013, we recognized $0.2 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 KL4 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 June 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 KL4 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 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 KL4 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 June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Product development and manufacturing	$ 4,998	$ 3,938	$ 11,822	$ 7,041
Medical and regulatory operations	1,459	1,251	2,910	2,074
Direct preclinical and clinical programs	406	17	603	624
Total Research & Development Expenses	$ 6,863	$ 5,206	$ 15,335	$ 9,739

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 June 30, 2013 and 2012, respectively; and $0.7 million and $0.8 million for the six months ended June 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 clinical and commercial drug supply for our KL4 surfactant products, in conformance with current good manufacturing practices (cGMP); (ii) design and development activities to prepare and manufacture CAG devices, primarily 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 June 30, 2013 increased $1.1 million as compared to the same period in 2012, primarily due to (i) costs of design, development and manufacturing activities related to preparing our CAG for use in our planned AEROSURF phase 2 clinical trials, which we expect to initiate in the fourth quarter of 2013, 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 (ii) costs associated with the technical transfer of our KL4 surfactant manufacturing processes to our CMO.

Product development and manufacturing expenses for the six months ended June 30, 2013 increased $4.8 million from the comparable period in 2012 primarily due to (i) costs of design, development and manufacturing activities related to the preparing our CAG for use in our planned AEROSURF phase 2 clinical trials, which we expect to initiate in the fourth quarter of 2013, 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 of our KL4 surfactant manufacturing processes to our CMO; and (iii) purchases of active pharmaceutical ingredients (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.

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 also 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 recently 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, which is nearly completed. We also have entered into a Supply Agreement with DSM, dated August 7, 2013, 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 have completed the technology transfer of our lyophilized KL4 surfactant manufacturing process to DSM and are currently finalizing an agreement with DSM that contemplates the further development and manufacture of our lyophilized KL4 surfactant for our pipeline development programs, primarily AEROSURF. 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 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. The extensive experience that we have gained from having owned our own manufacturing operations since 2005 can be leveraged flexibly to respond over time to support 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 three and six months ended June 30, 2013 increased $0.2 million and $0.8 million, respectively, compared to the same periods 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 potential Investigational New Drug (IND) and 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 months ended June 30, 2013 increased $0.4 million as compared to the same period in 2012 primarily due to (i) the purchase of component parts for use in the manufacture of clinic-ready CAG devices for our planned AEROSURF phase 2 clinical trials; and (ii) activities to support our response to recent FDA correspondence regarding our improved analytical chemistry test and updated product specifications for SURFAXIN drug product, which we submitted on June 7, 2013.

Direct preclinical and clinical programs expense for the six months ended June 30, 2013 were unchanged when compared to the same period in 2012. 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.

Our drug research and development activities are focused on the management of RDS in premature infants, currently AEROSURF and our lyophilized KL4 surfactant development programs. 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 plan to initiate the first phase of the AEROSURF phase 2 clinical 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 KL4 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 are initially focused on (i) the management of RDS in premature infants, including SURFAXIN liquid, and our lyophilized KL4 surfactant, which we are developing for use in our AEROSURF development program and potentially in a SURFAXIN LS development program; and (ii) development of our aerosol delivery technology, including preparation of a clinic-ready CAG device to support our planned phase 2 clinical program for AEROSURF to address RDS. 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."

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. As noted above, during the period of delay in the availability of SURFAXIN commercial drug product, we have made and plan to continue investments in our AEROSURF development program with a view to potentially initiating our planned phase 2 clinical program in the fourth quarter of 2013 and otherwise are pacing our investments in other development activities through the fourth quarter of 2012. *See*, "– Overview," and "– Liquidity and Capital Resources."

Selling, General and Administrative Expenses

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Selling, General and Administrative Expenses	$ 4,129	$ 3,610	$ 8,349	$ 5,657

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 three and six months ended June 30, 2013 increased $0.5 million and $2.7 million, respectively, 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.

In response to the delay in commercial availability of SURFAXIN drug product to potentially the fourth quarter of 2013, we are pacing certain of our planned investments through the fourth quarter of 2013, to conserve cash resources until we are able to secure the additional capital required to support our operations and development programs. However, we are continuing to invest in our medical affairs and commercial organization, and our marketing and field-based sales activities for SURFAXIN and AFECTAIR, and certain other key initiatives, including development activities to advance the AEROSURF program potentially to a planned phase 2 clinical program in the fourth quarter of 2013, which is expected to limit our ability to significantly reduce our cash outflows. *See*, "– Overview," and "– Liquidity and Capital Resources."

Change in Fair Value of Common Stock Warrant Liability

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Change in fair value of common stock warrant liability (Income / (Expense))	$ 2,525	$ 1,680	$ 2,686	$ (1,754)

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, in our 2012 Form 10-K, "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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Interest Expense	$ (343)	$ (4)	$ (520)	$ (8)

Interest expense in 2013 consists of interest expense associated with the Deerfield Facility 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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Cash interest expense	$ 218	$ –	$ 331	$ –
Non-cash amortization of debt discounts	118	–	177	–
Amortization of debt costs	5	–	8	–
Total Deerfield Facility interest expenses	$ 341	$ –	$ 516	$ –

Cash interest expense represents interest of 8.75% on the principal amount outstanding under the Deerfield Facility for the period that is to be paid in cash. Non-cash amortization of debt discount represents the amortization of transaction fees and the Black-Scholes pricing model 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 June 30, 2013, we had cash and cash equivalents of $31.3 million, approximately $6.7 million of accounts payable and accrued expenses, and $10 million of long-term debt under the Deerfield Facility, which also provides for an additional advance of $20 million to be paid upon the first commercial sale of SURFAXIN drug product, provided that such sale occurs on or before December 31, 2013. See, "– Loan Facility with Deerfield." Since the commercial availability of SURFAXIN drug product has been delayed until potentially the fourth quarter of 2013, the second Deerfield advance also has been delayed. To manage our resources during this delay, we reviewed and assessed our planned activities. We decided to maintain investments in our commercial and medical affairs capabilities and in our AEROSURF development program, in particular, the activities needed to initiate our planned AEROSURF phase 2 clinical program in the fourth quarter of 2013. To conserve cash resources, we implemented a plan to pace certain other investments in our operations and commercial and development programs through the fourth quarter of 2013. Before any financings, including under our ATM Program (see, "– Common Stock Offerings – At-the-Market Program (ATM Program)"), and before the expected $20 million advance under the Deerfield Facility, we anticipate that we have sufficient cash available to support our operations and debt service obligations into the first quarter of 2014.

Even if we succeed and SURFAXIN drug product and the AFECTAIR device are introduced commercially as planned and we secure the Deerfield additional $20 million advance to execute our business strategy and fund our operations over the long term, we will still 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. Such infusions of capital could come from potential strategic alliances and collaboration arrangements, debt financings, public offerings and other similar transactions. Since the $20 million advance under the Deerfield Facility is payable only if the first commercial sale of SURFAXIN drug product occurs on or before December 31, 2013, our access to funds under the Deerfield Facility could expire if we fail to complete the first commercial sale of SURFAXIN drug product in 2013. Given the time required to secure formulary acceptance of SURFAXIN at our target hospitals and acceptance of our new device, 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.

The accompanying interim unaudited financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. As a result of our year-end cash position, the audit opinion we received from our independent auditors for the year ended December 31, 2012 contains a notation related to our ability to continue as a going concern. Whether we can continue as a going concern is dependent upon our ability to raise additional capital, fund our commercial activities and development programs, and meet our obligations on a timely basis. If we are unable to secure sufficient additional capital, through potential strategic partnerships and collaborative arrangements, debt and/ or equity financings and other similar transactions, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to further limit our commercial activities and development programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to secure the necessary capital, we may be forced to curtail all activities and, ultimately, cease operations. Even if we are able to secure additional capital, such transactions may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Our June 30, 2013 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

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 expect that we may receive $20 million additional capital under our Deerfield Facility. Through our ATM Program, we have the ability to sell up to $25 million of common stock at such times and in such amounts that we deem appropriate. However, we may not gain access to the funds available under the Deerfield Facility and the ATM Program can be cancelled at any time by either party. We also plan to consider other public and private equity offerings as well as financing transactions, such as secured equipment financing facilities or other similar transactions.

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 initiation of the planned phase 2 clinical program in the fourth quarter of 2013; 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 SURFAXIN LS, in markets outside the U.S. We believe that our ability to enter into a significant strategic alliance will likely improve if we remain on track to initiate both the commercial sale of SURFAXIN and our AEROSURF phase 2 clinical program in the fourth quarter of 2013. 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.

As of June 30, 2013, 150 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 76.3 million shares of common stock were available for issuance and not otherwise reserved.

On May 15, 2013, we completed a public offering of 9.5 million shares of common stock, at a price of $1.50 per share resulting in net proceeds to us (after underwriter fees and anticipated expenses) of approximately $13.2 million. 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.

As of June 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 (Deerfield Warrants) in connection with the first advance under the Deerfield Facility. 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 warrants. In addition, 4.9 million are February 2011 five-year warrants, which 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 issued at an exercise price of $3.20 per share, which was thereafter adjusted downward, first to $2.80 per share following the public offering in March 2012 and then to $1.50 per share following the 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.

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. We require additional capital to satisfy our debt obligations, sustain operations, and complete the development and support the commercial introduction of our products, including SURFAXIN and AFECTAIR and, if approved, AEROSURF and potentially SURFAXIN LS. 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 June 30, 2013, we had cash and cash equivalents of $31.3 million compared to $26.9 million as of December 31, 2012. Cash outflows before financings for the six months ended June 30, 2013 consisted of $20.4 million used for ongoing operating activities and $0.1 million for purchases of property and equipment. Cash outflows before financings were offset by $10 million ($9.9 million net of expenses) advanced in February 2013 under the Deerfield Facility and $15.1 million of net proceeds from the May 2013 registered public offering.

Operating Activities

Net cash used in operating activities was $20.4 million and $14.0 million for the six months ended June 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 $2.7 million in 2013 and expense of $1.8 million in 2012), stock-based compensation, including our 401(k) match, and depreciation and amortization expenses ($1.9 million in 2013 and $1.7 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 prepare our CAG for use in our planned AEROSURF phase 2 clinical trials, which we expect to initiate in the fourth quarter of 2013, 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 active pharmaceutical ingredients (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 $0.1 million and $0.5 million for the six months ended June 30, 2013 and 2012, respectively.

Financing Activities

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

(in thousands)	Six Months Ended June 30, 2013	2012
Financings pursuant to common stock offerings	$ 15,110	$ 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	(37)	(39)
Exercise of stock options and warrants	1	6,741
Cash flows from financing activities, net	$ 24,924	$ 50,307

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 June 30, 2013, $61.9 million remained 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 60 days after the date of the prospectus supplement ending on July 9, 2013.

At-the-Market Program (ATM Program)

On February 11, 2013, we entered into an At-the-Market Equity Offering Sales Agreement (ATM Program) with Stifel pursuant to which Stifel, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell over a three-year period up to a maximum of $25 million of our common stock. We are not required to sell any common stock at any time during the term of the ATM Program. If we issue a sale notice to Stifel, we may designate the minimum price per share at which our common stock may be sold and the maximum number of shares that Stifel is directed to sell during any selling period. As a result, prices are expected to vary as between purchasers and during the term of the offering. Stifel may sell shares by any method deemed to be an "at-the-market" equity offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, which may include ordinary brokers' transactions on The Nasdaq Capital Market, or otherwise at market prices prevailing at the time of sale or prices related to such prevailing market prices, or as otherwise agreed by Stifel and us. The shares to be offered under the ATM Program are registered under the 2011 Universal Shelf.

The ATM Program will terminate upon the earliest of: (1) the sale of all shares of common stock issuable thereunder, (2) February 11, 2016 or (3) other termination in accordance with the terms of the related agreement. Either party may terminate the ATM Program at any time upon written notification to the other party in accordance with the related agreement.

We have agreed to pay Stifel a commission equal to 3.0% of the gross sales price of shares sold pursuant to the ATM Program. With the exception of expenses related to the shares of common stock, Stifel will be responsible for all of its own costs and expenses incurred in connection with the ATM Program.

Committed Equity Financing Facility (CEFF)

The 2010 Stock Purchase Agreement originally provided for the purchase by Kingsbridge Capital Limited of the lesser of up to 2.1 million shares of our common stock or a maximum of $35 million in shares, and expired on June 11, 2013 with 1.1 million shares available and not issued. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Committed Equity Financing Facility (CEFF)" in our 2012 Form 10-K for a detailed description of our CEFF.

Loan Facility with Deerfield

On February 13, 2013, we entered into a secured loan 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), provided that the Milestone Date occurs on or before December 31, 2013. The loan may be prepaid in whole or in part without penalty at any time. Any amounts received 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, including applicable milestones, 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 (Deerfield 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 have been classified as equity.

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

Note Payable	$	10,000
Unamortized discount		(3,799)
Long-term debt, net of discount	$	6,201

Contractual Obligations and Commitments

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

(in thousands)	2013	2014	2015	2016	2017	There-after	Total
Operating lease obligations	$ 540	$ 1,087	$ 949	$ 934	$ 935	$ 158	$ 4,603
Deerfield Loan Facility[1]	–	–	–	–	3,330	6,670	10,000
Equipment loan obligations	32	79	69	–	–	–	180
Total	$ 572	$ 1,166	$ 1,018	$ 934	$ 4,265	$ 6,828	$ 14,783

(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 June 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.

Delays in the commercial availability of SURFAXIN could have a material adverse effect on our ability to execute our business strategy and fund our operations.

In October 2012, we announced that, during a review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, we had determined that one of our analytical chemistry methods used to assess SURFAXIN drug product's conformance to specifications required improvement and that an update to product specifications would be necessary. Thereafter, we communicated our findings to the FDA, improved and validated the analytical method, and submitted updated product specifications to the FDA. In April 2013, we received a response from the FDA that requested clarification and provided recommendations regarding the recently updated product specifications for SURFAXIN. We completed the required work and submitted our response to the FDA on June 7, 2013. We anticipate that the FDA may take up to four months to review our submission, such that, if our plan is successful and confirmed by the FDA within this timeline, we expect to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013.

Even if the United States (U.S.) Food and Drug Administration (FDA) agrees with our recent response to its correspondence addressing our earlier submission concerning our improved analytical chemistry method and updated SURFAXIN® drug product specifications, the continuing delays in the commercial availability of SURFAXIN could have a material adverse effect on our ability to execute our business strategy and fund our operations.

Although we currently believe that we will be successful, there can be no assurance that the FDA will agree with our submission or respond to our request within the anticipated time. The FDA may require additional information that would require additional time. Moreover, we may identify unforeseen problems that have not yet been discovered that could adversely affect our plans. Any failure to satisfy any issues raised by the FDA could significantly delay, or preclude outright, our gaining agreement on acceptable updated product specifications, or could result in an action by the FDA to restrict our ability to commercialize some or all of our products, which could potentially delay or prevent the commercial availability of SURFAXIN drug product. There also can be no assurance that we will be able to retain our key commercial and medical affairs personnel until SURFAXIN is commercially available, or attract additional personnel when needed to support the commercial introduction of SURFAXIN and AFECTAIR®, our disposable, aerosol-conducting airway connector for infants.

We may be unable to secure 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 June 30, 2013, we have an accumulated deficit of approximately $456.0 million and we expect to continue to incur significant, increasing operating losses over the next several years. As of June 30, 2013, we had cash and cash equivalents of approximately $31.3 million and approximately $6.7 million of accounts payable and accrued expenses and $10 million of long-term debt under the Deerfield Facility. Before any financing, including under our ATM Program, and before the expected $20 million advance under the Deerfield Facility, we anticipate that we have sufficient cash available to support our operations and debt service obligations into the first quarter of 2014.

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, AFECTAIR 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*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources," and, in this Quarterly Report on Form 10-Q, "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 the Deerfield Facility and 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 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; or
- 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 have established our field-based sales and marketing and medical affairs organizations, and began enhancing 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. Moreover, the equity incentives in the form of options that we have issued are, for the most part, significantly devalued or out of the money.

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 six months ended June 30, 2013, we issued 15,000 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during 2013. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(2) of the Act.

ITEM 5. OTHER INFORMATION

Subsequent to our second fiscal quarter ended June 30, 2013, we entered into a Pharmaceutical Manufacturing and Supply Agreement with DSM Pharmaceuticals, Inc., dated August 7, 2013 (the "Supply Agreement"). Pursuant to the Supply Agreement, DSM will provide us with SURFAXIN drug product in finished liquid dosage form, for commercial use and other activities. The Supply Agreement contains the general terms and conditions for ordering and production of commercial supply, as well as certain specific economic terms for production of SURFAXIN drug product, including purchase commitments, price and delivery terms. Subject to earlier termination for various matters, including, without limitation, material breach, the initial term of the Agreement is through December 31, 2015, and is subject to such extensions as the parties may agree. In addition, the Supply Agreement contemplates that DSM will provide certain regulatory services and may provide additional consulting services as we may agree from time to time.

The foregoing summary of the DSM Agreement is not complete and is qualified in its entirety by reference to the DSM Agreement, a copy of which is filed as an exhibit to this Quarterly Report on Form 10-Q. The representations and warranties contained the DSM Agreement are not for the benefit of any party other than the parties to the DSM Agreement and are not intended as a document for investor or the public generally to obtain factual information about our company and business.

ITEM 6. EXHIBITS

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

SIGNATURES

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

Discovery Laboratories, Inc.
(Registrant)

Date: August 8, 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	Filed herewith.
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	Filed herewith.
10.2+	Pharmaceutical Manufacturing and Supply Agreement dated August 7, 2013 between Discovery and DSM Pharmaceuticals, Inc.	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 June 30, 2013, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of June 30, 2013 (unaudited) and December 31, 2012, (ii) Statements of Operations (unaudited) for the three and six months ended June 30, 2013 and June 30, 2012, (iii) Statements of Cash Flows (unaudited) for the six months ended June 30, 2013 and June 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.

* A management contract or compensatory plan or arrangement required to be filed as an exhibit to this quarterly report pursuant to Item 6 of Form 10-Q.

Exhibit 3.1

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
DISCOVERY LABORATORIES, INC.

(Pursuant to Sections 228, 242, and 245 of the
General Corporation Law of the State of Delaware)

The Corporation was originally incorporated on November 6, 1992, under the name "Ansan, Inc."

ARTICLE ONE

The name of the corporation (hereinafter called the "Corporation") is Discovery Laboratories, Inc.

ARTICLE TWO

The address, including street, number, city, and county, of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle; and the name of the registered agent of the Corporation in the State of Delaware at such address is The Corporation Trust Company.

ARTICLE THREE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

ARTICLE FOUR

The total number of shares of all classes of stock which the Corporation shall have the authority to issue is 155,000,000 consisting of 150,000,000 shares of common stock, par value $0.001 per share (the "Common Stock"), and 5,000,000 shares of preferred stock, par value $0.001 per share (the "Preferred Stock").

The Board of Directors may divide the Preferred Stock into any number of series, fix the designation and number of shares of each such series, and determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock. The Board of Directors (within the limits and restrictions of any resolutions adopted by it originally fixing the number of any shares of any series of Preferred Stock) may increase or decrease the number of shares initially fixed for any series, but no such decrease shall reduce the number below the number of shares then outstanding and shares duly reserved for issuance.

ARTICLE FIVE

In furtherance and not in limitation of the powers conferred by statute, the Board of Directors shall have the power, both before and after receipt of any payment for any of the Corporation's capital stock, to adopt, amend, repeal or otherwise alter the Bylaws of the Corporation without any action on the part of the stockholders; provided, however, that the grant of such power to the Board of Directors shall not divest the stockholders of nor limit their power to adopt, amend, repeal, or otherwise alter the Bylaws.

ARTICLE SIX

Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

ARTICLE SEVEN

The Corporation reserves the rights to adopt, repeal, rescind or amend in any respect any provisions contained in this Certificate of Incorporation in the manner now or hereafter prescribed by applicable law, and all rights conferred on stockholders herein are granted subject to this reservation.

ARTICLE EIGHT

A director of the Corporation shall, to the fullest extent permitted by the General Corporation Law of the State of Delaware as it now exists or as it may hereafter be amended, not be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Neither any amendment nor repeal of this Article EIGHT, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation inconsistent with this Article EIGHT, shall eliminate or reduce the effect of this Article EIGHT in respect of any matter occurring or any cause of action, suit or claim that, but for this Article EIGHT, would accrue or arise prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE NINE

This Amended and Restated Certificate of Incorporation was duly adopted in accordance with the provisions of Section 245 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, Discovery Laboratories, Inc., has caused this Amended and Restated Certificate of Incorporation to be signed by its duly authorized officer this 25th day of July, 2013.

Discovery Laboratories, Inc.

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

Exhibit 10.1

EXTENSION OF LEASE

This Extension of Lease, dated as of July 16, 2013, is by and between Norwell Land Company ("Landlord"), One Stamford Forum, Stamford, Connecticut, and Discovery Laboratories, Inc., successor-in-interest to Laureate Pharma, Inc. ("Tenant"), 700 Union Boulevard, Totowa, New Jersey;

WHEREAS, Landlord and Tenant have entered into that certain lease dated as of December 3, 2004, covering certain space located at 700 Union Boulevard, Totowa, New Jersey (the "Lease"); and

WHEREAS, the parties desire to amend the Lease, as hereinafter provided;

NOW, THEREFORE, it is hereby agreed as follows:

1. The term of the Lease is hereby extended to and including June 30, 2015.

2. Section 4.1 of the Lease is hereby amended to provide that during the period December 4, 2014 (“Effective Date of Renewal”) through June 30, 2015 (the “Extended Term”) the annual Base Rent shall be $525,000 and that the monthly installments thereof shall be in the amount of $43,750.

3. On the Effective Date of Renewal, Tenant shall pay to Landlord the sum of $306,250 as payment in full of Base Rent during the Extended Term.

4. On the Effective Date of Renewal, Tenant shall pay to Landlord a sum intended to fulfill Tenant’s obligations regarding Tenant’s Tax Payment and Tenant’s Expense Payment for the Extended Term (the “Estimated Expense Payment”). The Estimated Expense Payment shall be equal to the total of the Tenant’s Tax Payment and Tenant’s Expense Payment for the period from May 1, 2014 through November 30, 2014. If, at the end of the Term, the Estimated Expense Payment made was in excess of the Actual Expenses, Landlord shall, within sixty (60) days of the end of the Term, reimburse Tenant for the amount of such over-payment. In the event that the Estimated Expense Payment was less than the Actual Expenses, Tenant shall, within sixty (60) days of the end of the Term, reimburse Landlord for such additional amount.

5. Except as amended hereby, the Lease shall remain unmodified and in full force and effect. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Lease.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Extension of Lease as of the date first above written.

NORWELL LAND COMPANY	DISCOVERY LABORATORIES, INC.
By: Its Managing General Partner, Connecticut Avenue Realty Co., Inc.	
By: /s/ Diana Lenkowsky	By: /s/ John Cooper
Name: Diana Lenkowsky	Name: John Cooper
Title: Vice President	Title: President and Chief Executive Officer

Exhibit 10.2

[*] Denotes that confidential treatment of redacted portions has been requested.**

PHARMACEUTICAL MANUFACTURING AND SUPPLY AGREEMENT

Dated August 7, 2013

By and Between

DSM PHARMACEUTICALS, INC.
Greenville, NC

and

DISCOVERY LABORATORIES, INC.

[*] Denotes that confidential treatment of redacted portions has been requested.**

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[*] Denotes that confidential treatment of redacted portions has been requested.**

PHARMACEUTICAL MANUFACTURING
AND SUPPLY AGREEMENT
By and Between
DSM Pharmaceuticals, Inc. and
Discovery Laboratories, Inc.

THIS PHARMACEUTICAL MANUFACTURING AND SUPPLY AGREEMENT (this "Agreement") is made effective as of this 7th day of August 2013, by and between **DSM Pharmaceuticals, Inc**., a Delaware corporation with principal place of business at 5900 Martin Luther King Hwy., Greenville, North Carolina 27834 ("DSM") and **Discovery Laboratories, Inc.,** a Delaware corporation with principal place of business at 2600 Kelly Road, Suite 100, Warrington, PA 18976-3622 ("Discovery Labs"); (each individually a "Party" and collectively the "Parties").

W I T N E S S:

WHEREAS, Discovery Labs has obtained or will obtain, regulatory approval to market one or more pharmaceutical product(s), including SURFAXIN® (lucinactant) intratracheal suspension, in finished dosage form for human use; and

WHEREAS, DSM has the necessary knowledge, professional expertise, facilities, manufacturing authorization, equipment, and trained, competent personnel to manufacture the pharmaceutical product(s) for Discovery Labs; and

WHEREAS, Discovery Labs desires to establish DSM as a manufacturer of the pharmaceutical product(s), including SURFAXIN, and DSM desires to perform such services and to manufacture such product for Discovery Labs, all on the terms and conditions set forth in this Agreement; and

WHEREAS, Discovery Labs and DSM wish to currently enter into an agreement for the manufacture of SURFAXIN, and contemplate that DSM will also serve as a manufacturer for future products, including a lyophilized dosage form of lucinactant;

NOW THEREFORE, in consideration of the mutual covenants and promises set forth herein, the Parties agree as follows:

ARTICLE 1: DEFINITIONS

The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement:

1.1 Acquisition Cost. "Acquisition Cost" shall mean the actual invoiced price paid by either Party to any Third Party, including without limitation shipping and handling costs and customs duties, in connection with the acquisition of Active Pharmaceutical Ingredients, Excipients, packaging or other materials utilized in the production of Product hereunder.

1.2 Active Pharmaceutical Ingredients / API. "Active Pharmaceutical Ingredients" or "API" shall mean the active pharmaceutical ingredients for each Product to be manufactured hereunder, as set forth in the respective Product Addendum in **ANNEX 1**, including the specifications and the analytical methodology related thereto, as such specifications may be amended from time to time by mutual agreement of the Parties.

1.3 Affiliate. "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.

1.4 Agreement. "Agreement" shall mean this Supply Agreement.

1.5 Batch. "Batch" shall have the same meaning as Lot.

1.6 Cancelled Production Fee. "Cancelled Production Fee" shall have the meaning set forth in Section 4.4.3.

1.7 CGMP. "CGMP" means those practices in the manufacture of pharmaceutical products that are recognized as the current good manufacturing practices by the FDA in accordance with FDA regulations, guidelines, other administrative interpretations, and rulings in connection therewith, including but not limited to those regulations cited in 21 C.F.R. parts 210 and 211, all as they may be amended from time to time.

1.8 Commercial Product. "Commercial Product" shall mean Product supplied hereunder by DSM intended for commercial sale and/or human use.

1.9 Contract Year. "Contract Year" shall refer to the period commencing on the Effective Date and ending on December 31, 2013, and each successive twelve (12) month period thereafter during the term of this Agreement.

1.10 Delivery Date. "Delivery Date" shall mean a date for which delivery of Product is stated in a Purchase Order.

1.11 Designated Vendors. "Designated Vendors" shall have the meaning set forth in Section 4.44.

1.12 Developments. "Developments" means any and all inventions, discoveries, know-how, information, data, writings, and other Intellectual Property, in any form whatsoever, both tangible and intangible, developed by DSM or by Discovery Labs, or both, in the course of performance under this Agreement.

1.13 Development Product. "Development Product" shall mean Product not intended for commercial sale.

1.14 Discovery Labs' Method of Manufacture. "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 KL4-based pulmonary surfactants such as, for example, Product, exclusive of any DSM Intellectual Property.

1.15 Discovery Labs' Patents. "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.

1.16 Discovery Labs' Technology. "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 KL4 (sinapultide) and KL4 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.

1.17 Discovery Labs' Technology Package. "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.

1.18 Effective Date. "Effective Date" shall mean the date appearing at the beginning of this Agreement.

1.19 Excipients. "Excipients" shall mean the raw materials, other than Active Pharmaceutical Ingredients and packaging, required to manufacture each Product in accordance with the Product Specifications, as such Excipients are listed in the Product Addendum in **ANNEX 1** for each Product to be manufactured hereunder, including the specifications and the analytical methodology related thereto, as such specifications may be amended from time to time by mutual agreement of the Parties.

1.20 FD&C Act. "FD&C Act" shall mean the United States Federal Food, Drug and Cosmetic Act, as amended.

1.21 FDA. "FDA" shall mean the United States Food and Drug Administration, or any successor entity.

1.22 Firm Purchase Commitment. "Firm Purchase Commitment" shall mean the obligation of DSM to supply and of Discovery Labs to purchase, the quantities forecasted by Discovery Labs in accordance with Section 6.3 hereinafter.

1.23 First Commercial Sale. "First Commercial Sale" shall mean the first commercial sale of Commercial Product by Discovery Labs or its Affiliates in the Territory following Product Approval.

1.24 Freeze Dryer Capacity Reservation Fee. "Freeze Dryer Capacity Reservation Fee" shall mean that portion of the Product Price which relates to the reservation of production capacity in DSM's freeze dryer equipment for production of Products hereunder based on Discovery Labs Monthly Forecast.

1.25 Initial Term. "Initial Term" shall have the meaning set forth in Section 11.1 hereof.

1.26 Intellectual Property. "Intellectual Property" shall mean patents, copyrights, trademarks, trade names, trade secrets, know-how, service marks, licenses and other intellectual property rights which are owned by or licensed to a Party.

1.27 Invention. "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) in the course of performance under this Agreement.

1.28 Long Term Forecast. "Long Term Forecast" shall have the meaning set forth in Section 6.1 hereof.

1.29 Lot. "Lot" shall mean any of the following: (a) a development/clinical trial lot of Product; (b) a Validation Lot; or (c) with respect to Commercial Product, any size lot mutually agreed upon by the Parties and stated in **ANNEX 1**.

1.30 Monthly Forecast. "Monthly Forecast" shall have the meaning set forth in Section 6.2 hereof.

1.31 NDA or ANDA. "NDA" shall mean New Drug Application for the Product, as filed with the FDA; "ANDA" shall mean the Abbreviated New Drug Application for the Product, as filed with the FDA, whichever is applicable.

1.32 Packaging Specifications. "Packaging Specifications" shall mean the packaging and labeling specifications for the Product to be attached hereto as **ANNEX 1** and made a part hereof, as such specifications may be amended from time to time by mutual agreement of the Parties.

1.33 Party. "Party" or "Parties" shall refer to either DSM or Discovery Labs, or both, as the context so requires.

1.34 Product. "Product" shall mean the product which DSM agrees to manufacture, and Discovery Labs agrees to purchase hereunder, as more fully described in **ANNEX 1**.

1.35 Product Addendum. "Product Addendum" shall mean each product addendum attached to **ANNEX 1** and incorporated herein by reference, stating each Product to be manufactured and supplied hereunder, and including further information as provided in Section 2.2.

1.36 Product Approval. "Product Approval" shall mean final FDA approval of Discovery Labs New Drug Application ("NDA" or "ANDA") or other Regulatory Documentation.

1.37 Product Price. "Product Price" shall mean the Commercial Product price set forth in **ANNEX 1** attached hereto and made a part hereof, as such price may be amended from time to time in accordance with this Agreement.

1.38 Product Specifications. "Product Specifications" shall mean the specifications for the Product to be manufactured hereunder, as referenced in **ANNEX 1** and made a part hereof, as determined in accordance with the analytical methodology agreed upon by the Parties, as such specifications may be amended from time to time by mutual agreement of the Parties, including without limitation such amendments as may be required to obtain Product Approval.

1.39 Purchase Order. "Purchase Order" shall have the meaning set forth in Section 7.1.

1.40 Quality Agreement. "Quality Agreement" shall mean the Quality Agreement, as defined in Section 5.6.

1.41 SKU. "SKU" shall refer to individual stock keeping units of each Product hereunder.

1.42 Specifications. "Specifications" shall mean the Product Specifications and the Packaging Specifications.

1.43 Territory. "Territory" shall mean the United States of America, and its territories and possessions.

1.44 Third Party. "Third Party" or "Third Parties" shall mean any Party other than Discovery Labs, DSM and their respective Affiliates.

1.45 Unit. "Unit" shall mean a unit of Product according to the Product Addendum for such Product.

1.46 Validation Activities. "Validation Activities" shall mean those activities to be performed by DSM prior to the First Commercial Sale including, but not limited to, process qualification of content uniformity, analytical testing, preparation of validation technical reports, cleaning validation, manufacturing and testing of Validation Lots.

[*] Denotes that confidential treatment of redacted portions has been requested.**

1.47 Validation Lots. "Validation Lots" for a dosage form shall mean shall mean the initial number of Lots, which shall be at least **[***]**, of the Product which are manufactured by DSM during the course of the Validation Activities.

1.48 Discovery Labs Regulatory Documentation. "Discovery Labs Regulatory Documentation" shall mean documentation which Discovery Labs has filed with regulatory authorities relating to the formulation of the Product, and any supplements to such documentation as may be filed during the term hereof, including the NDA.

ARTICLE 2: SALE AND PURCHASE OF PRODUCT

2.1 Agreement to Purchase and Sell. During each Contract Year throughout the term of this Agreement, DSM agrees to manufacture and sell to Discovery Labs, and Discovery Labs agrees to purchase from DSM a minimum percentage of its requirements for each Product, for sale and/or distribution within the Territory (hereinafter "Minimum Purchase Commitment"), in accordance with the terms and subject to the conditions of this Agreement, including the ANNEXes hereto. The Minimum Purchase Commitment associated with each Product shall be set forth in the respective Product Addendum attached to **ANNEX 1**.

2.2 Product Addendums. Product Specifications and other information shall be set forth in each Product Addendum in **ANNEX 1**, and shall include or clearly reference (i) the Product Specifications, (ii) the Active Pharmaceutical Ingredients and specifications thereof; (iii) the Excipients and specifications thereof; (iv) the Packaging Specifications; (v) the Product Price and any specific price increase provisions; (vi) any special equipment required to be purchased to manufacture the Product pursuant to Section 4.1; (vii) lead times for Purchase Orders and inventories; (viii) take-or-pay or minimum and maximum quantities (as applicable); (ix) any special requirements for the procurement of API and/or Excipients; and (x) the Minimum Purchase Commitment terms (xi) Expected API Yield; (xii) Commercial Product Shelf Life; (xiii) Minimum Contract Quantities; and (xiv) Product Term. "Product Term" shall mean the period during which DSM agrees to manufacture and Discovery Labs agrees to purchase a particular Product under the terms of this Agreement and shall commence on the date that the Parties enter into the applicable Product Addendum and shall expire on the date set forth in the applicable Product Addendum.

2.3 Firm Purchase Commitment, Minimum Quantities. Discovery Labs' only obligation to purchase, and DSM's only obligation to sell, shall be those quantities referenced in Section 6.4.

2.4 Development. DSM agrees to supply Product as requested by Discovery Labs for development activities ("Development Product") in accordance with the prices set forth in **ANNEX 1**, subject to adjustment as set forth in Section 8.2 hereof. Any such quantities of

Development Product purchased by Discovery Labs from Validation Lots shall be included in the Firm Purchase Commitment for the applicable Contract Year. **[***]**

2.5 Disclosure/Development of Health Risk Data. Discovery Labs agrees to disclose to DSM material information which is or becomes available to Discovery Labs regarding health risks which may be involved in manufacturing any Product, including information regarding the specified Active Ingredients, Excipients, and other components. Such information shall include, without limitation, OSHA required information, information regarding occupational exposure limits, toxicology studies and reports, and other health-related data. If reasonable industrial hygiene data is not available, DSM and Discovery Labs will cooperate to develop necessary and reasonable data as mutually agreed.

2.6 Customs Requirements

2.6.1 C-TPAT Requirements. For Active Pharmaceutical Ingredients, Excipients, and/or other components supplied to DSM by or on behalf of Discovery Labs which may be subject to import or export, Discovery Labs agrees that vendors and carriers will comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism ("C-TPAT").

2.6.2 Customs Documentation and Valuations. For samples, documentation or Product delivered hereunder for export by Discovery Labs, Discovery Labs shall be responsible for arranging customs documentation and valuations directly or indirectly through its designated customers broker. If Discovery Labs requests DSM to assume these responsibilities, DSM shall utilize its designated customs broker and shall state customs valuations which appropriately reflect contract costs. DSM's reasonable costs in providing such customs services shall be invoiced to, and reimbursed by Discovery Labs. Discovery Labs shall be responsible for payment of all customs duties and related assessments.

ARTICLE 3: COORDINATORS; DIVESTMENT

3.1 Appointment of Coordinators. Within ten (10) days after the Effective Date hereof, Discovery Labs and DSM shall each appoint an authorized representative and a backup representative ("Coordinators") for the exchange of all communications, other than legal notices, related to the manufacturing, labeling and packaging of the Product. Each Party shall provide notice to the other Party as to the name and title of the individuals so appointed. Each Party may replace its Coordinators at any time for any reason by providing written notice to the other Party in accordance with Section 20.11 hereof.

3.2 Divestment of Products.

3.2.1 If during the term of this Agreement, Discovery Labs elects to assign or otherwise fully divest to any Third Party its drug rights to any Product (the "Divested Product") included in this Agreement, Discovery Labs shall so advise DSM. Although the terms and conditions of such divestment shall be completely within the control of Discovery Labs, the Parties agree that the terms and conditions of further development and/or manufacturing by DSM of such Divested Product under this Agreement shall be subject to renegotiation between DSM and the Third Party transferee of such drug rights. For the avoidance of doubt, this section 3.2 shall not apply in the event Discovery Labs out-licenses sales and marketing rights, or enters into another similar transaction whereby Discovery Labs remains responsible for manufacturing, such that it maintains its contractual relationship with DSM.

3.2.2 Notwithstanding Section 3.2.1, upon Discovery Labs' transfer of any Divested Product to a Third Party, DSM agrees to serve as an interim supplier of the Product to the Third Party under the terms of this Agreement for **[***]**, unless DSM and the Third Party agree to terminate the Agreement as to such Product or reach mutual agreement on new terms and conditions of continued supply.

3.2.3 Discovery Labs acknowledges and agrees that the terms of pricing, delivery, allocation of liability, and other terms set forth in this Agreement are specific to this Agreement and the Parties hereto, and may not be appropriate or equitable as applied to any Third Party. DSM agrees to negotiate in good faith to reach agreement with such Third Party in respect of continuation of any Divested Product under this Agreement.

3.2.4 Pending transfer of any Divested Product hereunder to a Third Party, Discovery Labs agrees to be responsible for any Firm Purchase Commitments, take-or-pay, or minimum purchase requirements which have accrued hereunder in respect of such Divested Product. Discovery Labs also agrees to be responsible for payment of purchased Product and FDA compliance with respect to any Divested Product until such time as Discovery Labs and the Third Party have completed the transfer by formal written assignment which is in form acceptable to DSM. Further, during the Interim Supply Period, Discovery Labs shall remain liable for failure of a Third Party transferee to deliver payment due to DSM in accordance with the terms of this Agreement, provided that Discovery Labs shall only remain liable to DSM under this Section 3.2.4 until such time as (i) DSM and the Third Party transferee reach mutual agreement on new terms and conditions for the continued supply of Product, (ii) DSM and the Third Party transferee agree to terminate the Agreement as to such Product, or (iii) the Interim Supply Period expires, whichever occurs first. DSM agrees to promptly notify Discovery Labs in the event DSM reaches agreement with the Third Party under new supply terms (including if the parties decide to continue the same supply terms as in this Agreement), or if DSM and the Third Party decides to terminate this Agreement.

3.2.5 **[***]**

ARTICLE 4: EQUIPMENT; API; EXCIPIENTS; ARTWORK

4.1 Equipment. Equipment owned by DSM and located at DSM's Greenville, North Carolina facility, shall not be dedicated to any single customer, but shall be available for manufacturing of product according to DSM's manufacturing processes requirements.

4.1.1 If special equipment is required to be purchased for the processing of the Product, then Discovery Labs and DSM shall mutually agree on the terms and conditions of purchase. Equipment which Discovery Labs has purchased or agreed to purchase, and for which it shall be financially responsible as to capital modifications as agreed by the Parties, shall be identified in **ANNEX 2** and shall be dedicated to the production of the Product(s). Discovery Labs may at times authorize DSM, with DSM's approval, to select and order equipment that will be invoiced directly to Discovery Labs. DSM shall be responsible for installing and qualifying at its facility, any and all new or used equipment, molds, and tooling necessary for the manufacturing, packaging, and labeling of the Product.

4.1.2 Equipment identified to be purchased by Discovery Labs for the Product and to be installed at DSM shall be identified in **ANNEX 2**. DSM shall obtain Discovery Labs prior written approval for all costs and expenses associated with such installation and qualification (including without limitation labor and engineering costs) of all equipment purchased by Discovery Labs and Discovery Labs shall reimburse DSM for all such reasonable costs according to the payment terms in section 8.4.

4.1.3 Title to all such equipment, molds and tooling paid for by Discovery Labs shall be retained by Discovery Labs. All such equipment, molds and tooling shall remain at DSM's facility for use by DSM for the manufacture of Product during the term of this Agreement unless otherwise stated herein.

4.1.4 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.

4.1.5 In connection with the purchase of any special equipment pursuant to this section 4.1, DSM shall provide Discovery Labs with reasonable assistance and administrative support related to the purchase or financing of such equipment. 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, upon the request of Discovery Labs, DSM agrees to clearly label any such equipment as being the property of Discovery Labs and DSM agrees not to remove, modify, or deface the label while the equipment remains at DSM's site and while Discovery Labs continues to own such equipment.

4.2 Active Pharmaceutical Ingredients and Excipients Supply.

4.2.1 Supply of API, Excipients. Discovery Labs shall supply Active Pharmaceutical Ingredients meeting the specifications set forth or referenced in **ANNEX 1** for production of the Product hereunder. DSM will supply Excipients and all other materials required to manufacture, test, package, label, and release the Product; and such Excipients and other materials shall meet the specifications set forth in the applicable Product Addendum. Packaging Specifications are also set forth or referenced in **ANNEX 1**.

4.2.2 Title to API. Discovery Labs shall retain all rights, title and interest in and to Active Pharmaceutical Ingredients (and any other materials) supplied by Discovery Labs for the production of Product hereunder.

4.2.3 Timely Delivery of API. In accordance with Section 6.5 hereinafter, Discovery Labs agrees to supply API to DSM on a timely basis, with lead times as set forth in **ANNEX 1**, so as to enable DSM to receive, inspect, and prepare such API for production according to the schedule established by DSM. Discovery Labs shall be responsible for any non-conforming API and/or production delays resulting therefrom.

4.2.4 Consumption/Loss of API. The expected yield (the "Expected Yield") of finished Product per unit of API utilized in the production of Product hereunder is set forth in Annex 1. The actual yield of finished Product (the "Average Consumption Ratio") shall be determined on an annual basis as the average consumption of API per unit of finished Product for all batches produced during the Contract Year. **[***]** DSM shall, in any case, not be liable for API loss relating to excessive variability in the production processes over which DSM has no control, nor for any losses relating to changes in the Specifications and/or production processes required by Discovery Labs. **[***]**

4.2.5 Adventitious Viruses. [Intentionally Left Blank]

4.2.6 Reimbursement of Costs. Discovery Labs further agrees to reimburse DSM for (i) reasonable costs incurred by DSM in decontaminating its production facilities as a result of contamination determined to be caused by Discovery Labs API and for (ii) any direct damages suffered by DSM from a third party claim resulting from such contamination; provided that the foregoing obligations shall not apply to API contamination that occurs after delivery of API to DSM and DSM's satisfactory inspection and testing of such API.

4.2.7 Latent Defects. Discovery Labs shall be responsible for all rejected Lots and recall expenses relating to latent defects in the API which could not reasonably have been discovered by DSM in the course of inspection and testing of material according to cGMP and applicable SOPs.

4.3 Artwork. Discovery Labs shall provide at no cost to DSM **[***]**, final camera ready artwork meeting the Packaging Specifications for all packaging components to be used in the manufacture of the Product for which new or modified artwork is required.

4.4 Vendors Designated or Contracted By Discovery Labs. If Discovery Labs elects, at its sole discretion, to require DSM to procure Excipients from specific vendors designated by Discovery Labs which are not approved vendors under contract with DSM (hereinafter, "Designated Vendors"), then Discovery Labs shall so advise DSM in writing, and DSM will establish supply arrangements with such Designated Vendors in accordance with this Section 4.4.

4.4.1 Cooperation on Supply Problems. DSM shall promptly advise Discovery Labs if it encounters supply problems, including delays and/or delivery of non-conforming products from Designated Vendors; and (ii) DSM and Discovery Labs shall cooperate to reduce or eliminate any supply problems from such Designated Vendors.

4.4.2 Annual Certification. Discovery Labs shall be obligated to certify its own Designated Vendors, as specified in the Quality Agreement, on an annual basis, at its expense, and shall annually supply certification to DSM for such Designated Vendors. If DSM is required to certify such Designated Vendors, DSM's certification expenses shall be reimbursed by Discovery Labs.

4.4.3 Cancelled Production Runs. If scheduled production runs are required to be cancelled because a Designated Vendor failed to supply acceptable materials on a timely basis, **[***]**.

4.4.4 Failed Batches. If any Batch of Product fails solely because of defects or other non-conformities in API or Raw Materials supplied by a Designated Vendor, **[***]**.

4.4.5 Rescheduled Runs. DSM shall not be obligated to re-schedule any production run which is cancelled due to Designated Vendor problems. If the production run cannot reasonably be rescheduled, then upon Discovery Labs payment of the Cancelled Production Fee, the quantities so cancelled shall be deducted from the Firm Purchase Commitment. However, if DSM is able to reschedule the cancelled production, then the full Product Price shall be charged for such rescheduled quantities upon completion, **[***]**.

4.4.6 Quality Issues. Discovery Labs shall be responsible for compensating DSM at cost for all resources required to investigate and resolve quality issues arising with the Designated Vendor.

4.4.7 Direct Contracts with Vendor. If Discovery Labs requires DSM to procure Excipients directly from any Designated Vendor, then DSM shall require that such Designated Vendor enter into a supply contract directly with DSM.

ARTICLE 5: WARRANTIES; SPECIFICATIONS; QUALITY

5.1 Warranties by DSM. DSM warrants to Discovery Labs that the Commercial Product, at the time of sale and shipment to Discovery Labs by DSM, (a) will conform to the Specifications as then in effect; (b) will have been manufactured in compliance with all applicable laws and regulations and in accordance with CGMP; (c) will not be (i) adulterated or misbranded by DSM within the meaning of the FD&C Act nor (ii) an article that may not be introduced into interstate commerce under the provisions of Sections 404 or 505 of the FD&C Act; and (d) shall (except for pre-validation and pre-launch Lots) have a minimum Commercial Product shelf life, as set forth in ANNEX 1, at the time of delivery to Discovery Labs. If Discovery Labs elects to conduct its own Batch record reviews, the remaining shelf life required hereunder shall be correspondingly reduced for the period of time required by Discovery Labs for such review.

DSM warrants to Discovery Labs that any Validation Lots will be produced in accordance with the Specifications then in effect.

5.2 Disclaimer by DSM. **DSM expressly disclaims (a) any warranty that the Products (i) will be merchantable, (ii) will be fit for any particular purpose, or (iii) will not violate or infringe the patent or other intellectual property rights of third Parties as to formulation or composition; (b) any other warranties with respect to the Product, express or implied, except as expressly stated in this Agreement; and (c) any warranties in respect of the formulation, composition, use, or distribution of the Product or in respect of the marketing and/or sale of the Product to third parties.**

5.3 Warranties by Discovery Labs. Discovery Labs represents and warrants to DSM that (a) the formulation, composition, use, distribution, marketing, and/or sale of the Products shall comply with regulatory requirements and applicable law, and that Discovery Labs will maintain all obligations with respect thereto; (b) that Discovery Labs will comply with applicable law and that it will keep DSM reasonably informed of any development which would affect DSM's production of the Products hereunder; (c) that in the event Discovery Labs ships Product outside of the United States, Discovery Labs will comply fully with all export administration and control laws and regulations of the United States government as may be applicable to the export, resale or other disposition of any Products purchased from DSM; (d) that Products manufactured in accordance with the Specifications will not infringe any patent or other intellectual property right of any Third Party; (e) that Excipients, API, and any production processes provided or specified by Discovery Labs will be suitable for the production of the Product; (f) that Discovery Labs has disclosed all information available to it regarding heath risks which may be involved in manufacturing any Product hereunder utilizing the specified Active Ingredients, Excipients, and other components; and (g) any API provided by Discovery Labs for the production of steriles products will not contain any adventitious viruses or other active deleterious substances which could contaminate the production processes or other operations of DSM.

5.4 Limitation of Liability. **Notwithstanding the foregoing warranties and representations and the further obligations of the Parties hereunder, in no event shall [***]. The Parties further agree that [***].**

5.5 Specification Changes.

5.5.1 If, for whatever reasons, Discovery Labs changes the Specifications, Discovery Labs shall promptly advise DSM in writing of such changes; and if such changes directly impact DSM's scheduling or costs, DSM shall promptly advise Discovery Labs as to any scheduling and/or price adjustments caused by such changes. Prior to implementation of such changes, the Parties agree to negotiate in good faith in an attempt to reach agreement on (a) the new price for any Product which embodies such changes, reflecting any increases to DSM in the cost or quantities of materials consumed, provided that the price shall not change more than the direct effect of such changes on DSM's costs for the Product, and (b) any other amendments to this Agreement which may be necessitated by such changes (e.g., an adjustment to the lead time for Purchase Orders), said changes to be in writing and signed by both parties.

5.5.2 Discovery Labs agrees to reimburse DSM for the reasonable expenses incurred by DSM as a result of such agreed-upon changes, including, but not limited to, reimbursing DSM for its validation and development costs, capital expenditure costs and costs for any packaging components or other materials rendered unusable as a result of such changes.

5.5.3 If during the term of this Agreement Discovery Labs amends or is required by law to amend the Specifications so as to render the Active Pharmaceutical Ingredients, Excipients and/or packaging components for any Product obsolete, Discovery Labs shall at Discovery Labs option, purchase from DSM, at DSM's Acquisition Cost, that amount of inventory of Excipients and packaging components so rendered obsolete, or accept DSM's return of such materials to Discovery Labs and reimburse DSM any restocking fees incurred; and Discovery Labs shall also purchase from DSM, at the applicable Product Price, that amount of inventory of Product which is rendered obsolete. **[***]**

5.5.4 DSM shall not make any change to the Specifications without Discovery Labs prior written consent.

5.6 Quality Agreement. 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.

5.7 Duty of Cooperation. The Parties acknowledge that production of pharmaceutical products is inherently complex and requires close attention to all aspects of the Specifications, Excipients, Active Pharmaceutical Ingredients, production, storage, and shipment (collectively, "Process Requirements"). The Parties further acknowledge that DSM, as manufacturer of the Products, and Discovery Labs, as distributor of the finished Products, have significant regulatory obligations. Accordingly, the Parties agree to comply with applicable law as to their respective obligations and to cooperate with each other to maintain regulatory compliance hereunder. The Parties further agree to notify each other promptly of any known problems with respect to Process Requirements and/or regulatory obligations and to resolve such problems in a prompt and efficient manner so as to permit continued production and shipment of conforming Product, in accordance with all applicable regulatory requirements. Costs for correction of any such Process Requirements shall be allocated between the Parties in a fair and equitable manner and in accordance with the respective obligations of the Parties hereunder and under any related agreements. If Discovery Labs elects to delay or cease production of the Product, for any period of time and for any reasons (except for delays or cessation of production caused by DSM or periodic short-term cessations as set forth in the Monthly Forecast), it shall promptly notify DSM; and Discovery Labs shall reimburse DSM for (i) DSM's costs incurred prior to or during such period of delay, including DSM's Acquisition Costs for unused inventories of Excipients, Active Pharmaceutical Ingredients, and finished Product produced in accordance with Discovery Labs forecasts, and (ii) DSM's reasonable costs for services in resolving problems with Process Requirements which are beyond the obligation or reasonable control of DSM; provided, however, that the foregoing applies only (a) to the extent DSM would not have incurred such costs (i) and (ii) if Discovery Labs had not delayed or ceased production of the Product, and (b) to the extent that such costs (i) and (ii) are not duplicative of any fees paid pursuant to section 6.3. Such election by Discovery Labs to delay or cease production of Product shall not relieve it from any Firm Purchase Commitment requirements or other purchase obligations.

ARTICLE 6: FORECASTS; ORDERS

6.1 Long Term Forecast. Within **[***]** after the Effective Date, Discovery Labs shall deliver to DSM a non-binding **[***]** forecast of Discovery Labs' quantity requirements for each Commercial Product or Development Product and for each Contract Year during the Initial Term (the "Long Term Forecast"). The Long Term Forecast shall thereafter be updated **[***]** during the Term of this Agreement. If DSM is unable to accommodate any portion of the Long Term Forecast, it shall notify Discovery Labs and the Parties shall agree on any revisions to the forecast. **[***]**

6.2 Monthly Forecast. Within **[***]**, Discovery Labs shall submit to DSM a written non-binding estimate of its monthly requirements for each Product for **[***]** (the "Monthly Forecast"). The Monthly Forecast shall be updated **[***]**. If Discovery Labs fails to update the Monthly Forecast, then DSM shall apply Discovery Labs most recently forecasted requirements in planning the production schedule; and Discovery Labs shall be obligated to purchase such quantities to the extent that they become part of the Firm Purchase Commitment. If DSM is unable to accept (i) quantities stated for any new month in the Monthly Forecast, or (ii) quantities in excess of previously forecasted quantities (collectively, the quantities in (i) and (ii) referred to as "Additional Quantities"), then DSM shall notify Discovery Labs in writing within **[***]**; otherwise such Additional Quantities shall be deemed to have been approved and accepted by DSM. The Parties shall negotiate in good faith to resolve any issues in respect of the Additional Quantities which DSM is unable to accept for any month(s) stated in the Monthly forecast, according to DSM's available capacity.

6.3 Firm Purchase Commitment. The forecast **[***]** contained in any Monthly Forecast shall always constitute a firm purchase commitment (the "Firm Purchase Commitment") and such forecast shall state in detail the quantities of Products ordered and the required delivery dates, and shall be binding on the Parties regarding Products to be purchased. The forecast for the **[***]** period of the Monthly Forecast is for planning purposes only and shall not constitute a commitment to purchase or supply Product. **[***]** However, if DSM is unable for any reason, other than the failure of Discovery Labs' Designated Vendors timely to provide API and/or Excipients as referenced in Section 4.4, to supply the Firm Purchase Commitment to Discovery Labs, Discovery Labs shall not be obligated to pay for that portion of the Firm Purchase Commitment which DSM could not deliver, and other minimum purchase requirements or contract quantities shall be adjusted proportionately for that Contract Year by the amount that DSM was unable to deliver.

6.4 Minimum Contract Quantities. In addition to the Firm Purchase Commitment and any quantities stated in Purchase Orders issued by Discovery Labs and accepted by DSM, Discovery Labs also agrees to purchase any minimum annual or contract quantities stated in the respective Product Addendum attached hereto as **ANNEX 1.**

6.5 Materials/Lead Times. DSM shall have the right, at any time, to order Excipients, and other materials necessary for the manufacture of Products in accordance with the lead-times set forth in **ANNEX 1** hereto. In addition, if due to unanticipated circumstances, any Raw Materials require a longer lead-time, DSM shall be entitled to order such materials as it deems appropriate to fulfill its obligations hereunder; provided that DSM shall notify Discovery Labs before any such order.

6.6 Quantities in Excess of Forecasts. Should any Purchase Order seek to purchase Product in amounts substantially in excess of amounts set forth in the most recent Monthly Forecast provided by Discovery Labs to DSM pursuant to Section 6.2 hereof, or should Discovery Labs desire to increase the amount of Product to be manufactured pursuant to any Purchase Order already submitted, then DSM shall use reasonable commercial efforts to comply with such requested changes; but DSM shall not be liable to Discovery Labs for any inability, despite its reasonable best efforts, to manufacture such excess quantities.

6.7 Zero Quantities. If Discovery Labs forecasts zero (0) quantities of Products for a period of **[***]** during the term of this Agreement (the "Zero Forecast Period"), then DSM shall have the option, at its sole discretion, to provide a **[***]** notice to Discovery Labs of DSM's intention to terminate the contract on a stated day within the Zero Forecast Period; and Discovery Labs shall thereafter have **[***]** either (i) to withdraw the zero forecasts and re-submit a reasonable quantity forecast, or (ii) to negotiate other terms and conditions on which this Agreement shall remain in force and effect; otherwise, DSM shall have the right to terminate this Agreement at the end of the **[***]** notice period. This provision shall not apply until the time that DSM has been fully qualified by the FDA to manufacture the Product.

6.8 Business Interruption/Allocation. If for any reason DSM experiences a business interruption or plant outage that prevents DSM from supplying full contract quantities for any period of time, then DSM shall give due notice of such conditions to its customers, including Discovery Labs. **[***]** Except as hereinafter set forth, Discovery Labs shall be accorded equal treatment as among all DSM customers and then-current production commitments, subject to the following priorities:

6.8.1 **[***]**

6.8.2 **[***]** and

6.8.3 **[***]**

6.9 Obsolete Stock. Discovery Labs shall have the responsibility to reimburse DSM for the Acquisition Cost of all materials identified in Section 6.5, that DSM has ordered pursuant to Section 6.5 for the manufacture of Products, where such materials have expired, exceeded their shelf life or are rendered obsolete due to changes in artwork or regulation changes and can no longer be used in the manufacture of Products ("Obsolete Stock"). **[***]** DSM shall invoice Discovery Labs for the Acquisition Cost, administrative fee, and destruction costs within **[***]**. Customer shall submit payment to DSM according to the terms set forth in section 8.4.

ARTICLE 7: PURCHASE OF PRODUCT; DELIVERIES

7.1 Purchase Orders.

7.1.1 Except to the extent the Parties may otherwise agree with respect to a particular shipment, all Products shall be ordered by Discovery Labs pursuant to written Purchase Order ("Purchase Order"), stating the Product, Unit quantities, and Delivery Dates, which shall be sent to DSM not less than **[***]**. The Purchase Orders shall be consistent with the then-current Monthly Forecast. Upon receipt of each Purchase Order by DSM hereunder, DSM shall supply the Product(s), in such quantities (with any variances permitted hereunder) and shall use its best efforts to deliver such Product(s) to Discovery Labs no later than **[***]** after the Delivery Dates specified in such Purchase Order.

7.1.2 Changes in Purchase Orders. Once received by DSM, Purchase Orders are firm and may not be cancelled or modified without DSM's prior written consent, which shall not be unreasonably withheld or delayed.

7.1.3 Minimum Purchase Requirements Not Affected. If Discovery Labs requests changes, delays, or cancellation of any Purchase Order, and if DSM accepts such change, delay, or cancellation, DSM's acceptance shall not reduce or eliminate Discovery Labs' Firm Purchase Commitment and any other minimum purchase requirements. Such Firm Purchase Commitments and other minimum purchase requirements shall be based on actual quantities purchased and delivered during the relevant period.

7.1.4 Additional Terms. 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.

7.2 Purchase Quantities. All Product shall be ordered in Lot sizes or whole multiples thereof. Each Purchase Order shall specify the quantity of Units of Product being ordered. Quantities actually shipped pursuant to a given Purchase Order may vary from the quantities reflected in such Purchase Order by **[***]** and still be deemed to be in compliance with such Purchase Order; however Discovery Labs shall only be invoiced for actual delivered quantities.

7.3 Delivery Terms. The terms of delivery for the Product shall be F.O.B. DSM's Greenville, North Carolina plant. Title and risk of loss and/or damage to the Product shall pass to Discovery Labs upon delivery of the Product to the carrier at DSM's Greenville, North Carolina plant. All Products shall be properly prepared for safe and lawful shipment by DSM; shall be shipped to Discovery Labs distribution center or other location designated by Discovery Labs, via the common carrier mutually agreed upon by the Parties; and shall be accompanied by appropriate transportation and other agreed upon documentation. No products of any Third Party shall be shipped with the Products. Shipping costs actually prepaid by DSM will be billed to Discovery Labs monthly by DSM on separate invoices.

7.4 Invoicing. DSM shall invoice Discovery Labs upon shipment of finished Product in accordance with Section 8.4 hereinafter. Validation Lots and pre-launch Commercial Product shall be invoiced in accordance with Section 2.4, irrespective of whether or not Product Approval has been granted by the FDA.

7.5 Import and Export Matters. Discovery Labs will prepare, obtain, and maintain all necessary import and export registrations relating to the Product and the Active Pharmaceutical Ingredients. 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 for sale and/or marketing within countries outside the Territory, 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. Upon achievement of compliance, the definition of Territory, Section1.43, shall be amended to reflect the addition of other countries; and any additional costs incurred by DSM for registrations, fees, foreign regulatory compliance, and other related costs shall be for Discovery Labs account.

ARTICLE 8: PRICE; PRICE INCREASES; ADDITIONAL PAYMENTS

8.1 Price. For Product purchased during the first Contract Year, Discovery Labs shall pay to DSM the Product Price set forth in **ANNEX 1** hereto, subject to adjustment as set forth in Section 8.2 hereof.

8.2 Price Increases.

8.2.1 Designated Vendors. Any price increase in Excipients as implemented by Designated Vendors shall be passed through directly to Discovery Labs by a corresponding increase in the Product Prices which directly reflects such increase, **[***]**. As soon as DSM becomes aware of such price increases from a Designated Vendor, it shall provide notice and reasonable documentation supporting such price increases to Discovery Labs, stating the effective date and the amount of the increase in the Product Price.

8.2.2 Annual Increase. The Product Price may be increased by DSM as of January 1, 2015 and each Contract Year thereafter by a percentage amount equal to the percentage increase in the Producer Price Index (Pharmaceutical Preparations, PCU #325412, hereinafter referred to as the "PPI"), published by the United States Department of Labor, Bureau of Labor Statistics, or comparable successor index, during the twelve (12) month period ending with the most recent month for which published monthly statistics are available as of the first day of the new Contract Year. Increases in the Product Price pursuant to this Section 8.2.2 shall apply to all shipments during such Contract Year.

8.2.3 Increased Processing Costs. The Product Price may also be increased by DSM, upon written notice and provision of reasonable documentation supporting such price increases to Discovery Labs following startup of production hereunder, relating to increased costs for extended processing times, revised Specifications, or other process requirements which exceed the initial assumptions and parameters, provided that any such increases of more than **[***]** shall only be payable by Discovery Labs after **[***]** written notice. The Parties shall negotiate in good faith to conclude agreement on Product pricing which fairly reflects such increased costs.

8.2.4 Compliance with Regulatory Authorities. Additional payments or price increases may also be required to comply with regulatory requirements, fees, and other expenses incurred by DSM for importation of Product into additional foreign countries outside the Territory, in accordance with Section 7.5, or for expenses incurred by DSM to comply with material changes in regulatory requirements within the Territory (to the extent not previously contemplated). Any such price increases shall be limited to reflect the actual costs incurred by DSM as a result of compliance with said requirements, and shall be based on provision of reasonable documentation to Discovery Labs supporting such increase.

8.2.5 Specification Changes. The Product Price may also be increased by DSM as a result of Specification changes by Discovery Labs as referenced in Section 5.5, such price increase to reflect DSM's actual costs as a result of said Specification changes.

8.3 Taxes. The Product Prices set forth in the Product Addendum in **ANNEX 1** do not include sales, use, consumption, or excise taxes of any taxing authority. The amount of such taxes, if any, will be added to the Product Prices in effect at the time of shipment thereof and shall be reflected in the invoices submitted to Discovery Labs by DSM pursuant to this Agreement. Discovery Labs shall pay the amount of such taxes to DSM in accordance with the payment provisions of this Agreement.

8.4 Invoicing; Method of Payment. At the time of each shipment of Product hereunder, DSM shall invoice Discovery Labs. Discovery Labs shall pay such invoices for Product and any other payments due under this Agreement within **[***]** All payments due hereunder to DSM shall be sent to DSM at the times set forth herein by check or wire transfer to such accounts as DSM may designate to Discovery Labs in writing from time to time in accordance with Section 20.11 hereof. After the initiation of any wire transfer to DSM, Discovery Labs shall notify DSM's cash management department, as DSM may direct from time to time in accordance with Section 20.11.

8.5 Audit. Discovery Labs shall have the option, on an annual calendar-year basis, to request an audit of any Product prices or other charges invoiced by DSM during the preceding year. Such audits shall be performed by an independent certified public accountant, mutually agreeable to Discovery Labs and DSM (the "Independent Auditor"), who shall be permitted to review DSM's records and accounts relating to this Agreement to verify that invoices issued hereunder were correctly prepared. The Independent Auditor shall only report to Discovery Labs whether the invoices were correctly calculated; and if not, the amount by which the invoices were over-stated or under-stated. Discovery Labs shall not otherwise have access to the financial records of DSM. The Independent Auditor shall be subject to the confidentiality provisions set forth in Article 14. Promptly following the report of the Independent Auditor, the Parties shall resolve any over-charges or under-charges in good faith.

ARTICLE 9: RECALLS

9.1 Product recalls and FDA contacts relating to recall of Product shall be the responsibility of, and under the control of, Discovery Labs. However, in the event that either Party has reason to believe that any Products should be recalled or withdrawn from distribution, such Party shall promptly inform the other in writing prior to taking any such action. Discovery Labs shall notify the FDA, DEA, or any foreign regulatory agencies of any recall, and shall be responsible for coordinating all necessary activities regarding the action taken, to the extent required by law or deemed advisable by Discovery Labs. DSM and Discovery Labs acknowledge that each Party has significant regulatory obligations; and accordingly, each Party shall fully cooperate with the other to complete the recall, and shall thereafter resolve any allocation of liability as may be appropriate in accordance with the terms of this Agreement.

9.2 If any Product is recalled as a result of the supply by DSM of Product that does not conform to the Specifications or other Product requirements of this Agreement, then subject to Sections 4.2.7 and 5.3, DSM shall reimburse Discovery Labs for its reasonable expenses actually incurred as a result of such recall. If Discovery Labs elects to utilize a Third Party to conduct a recall, Discovery Labs shall so notify DSM of such Third Party utilized as soon as reasonably practical.

9.3 If each Party contributes to the cause for a recall, the expenses actually incurred as a result of such recall will be shared in proportion to each Party's responsibility. All other recalls of Product shall be at Discovery Labs sole expense. Discovery Labs shall give DSM prompt written notice of any Product recalls that Discovery Labs believes were caused or may have been caused by DSM's failure to comply with this Agreement or the Specifications.

9.4 Discovery Labs shall maintain records of all sales of Commercial Product and customers sufficient to adequately administer a recall, market withdrawal or correction for a period of five (5) years after termination or expiration of this Agreement. Subject to Section 9.1, Discovery Labs shall in all events be responsible for conducting any recalls, market withdrawals or corrections with respect to the Product.

9.5 Over-Labeling. DSM shall not be responsible for reimbursing Discovery Labs for Product recalls which result from over-labeling or re-labeling of Product which is effected by Discovery Labs or any third party, after Product has been delivered by DSM to Discovery Labs. Discovery Labs shall indemnify and hold DSM harmless from any liability related to such over-labeling.

ARTICLE 10: VALIDATION; REGULATORY

10.1 Validation.

10.1.1 DSM shall prepare equipment qualification and manufacturing validation procedures, and shall perform qualification and re-qualification of equipment, systems, and utilities as well as validation of the manufacturing, packaging and cleaning processes in accordance with such procedures.

10.1.2 The Parties recognize that the Validation Lots are being manufactured in part to validate their manufacturability and conformity to the Specifications. Therefore, any part of the Validation Lots which the Parties determine does not meet the Specifications shall not be subject to the warranty contained in Section 5.1 hereof or to the claims procedures set forth in Section 12.1 hereof; and, unless the failure of such nonconforming Validation Lot is due to the negligence or fault of DSM, Discovery Labs shall pay DSM the full Product Price for such nonconforming Validation Lots as set forth in Section 8.1 hereof. Discovery Labs shall not pay DSM for Validation Lots which fail to meet the Specifications due to the fault or negligence of DSM.

10.2 Regulatory.

10.2.1 DSM will provide Discovery Labs with standard regulatory support as identified under the heading "Regulatory Support" in **ANNEX 3** attached hereto. DSM shall also make available to Discovery Labs, at Discovery Labs' request and expense, additional regulatory consulting services as identified under the heading "Regulatory Consulting" in **ANNEX 3** attached hereto. Regulatory support services, as identified in **ANNEX 3**, shall be at no additional charge to Discovery Labs; regulatory consulting services shall be billed at DSM's then current standard hourly rates and payable pursuant to Section 7.4 of this Agreement. Additional regulatory services and/or documentation may be provided by DSM, subject to the advance agreement of the Parties and subject to additional charges.

10.2.2 Discovery Labs shall provide DSM with all documents reasonably requested by DSM relating to the FDA's pre-approval inspection of DSM's manufacturing facility, including, but not limited to, development reports, CMC sections of Discovery Labs' NDA or other Regulatory Documentation and stability data. In addition, Discovery Labs shall provide to DSM a copy of Discovery Labs' annual report with respect to the manufacture and control of the Product; and Discovery Labs shall take into consideration any DSM comments to such annual report with respect to the Product. DSM shall provide comments on the Annual Report to Discovery Labs within three (3) business days after receipt. Notwithstanding the foregoing or anything in this Agreement to the contrary, Discovery Labs shall be solely responsible for the CMC regulatory strategy.

10.3 Analytical and Validation Methodology. Any analytical and validation methodology supplied by Discovery Labs and required for use by DSM in the production of Product hereunder (i) must be certified by Discovery Labs to be appropriate for the intended use (e.g., cleaning verification, product release, in-process testing, and stability testing), (ii) must be validated per current regulatory guidelines, and (iii) must be readily available to DSM personnel during any regulatory inspection in the DSM site. Periodic re-certification of methods validations may be required in accordance with CGMP. Required analytical and validation methodology which is not supplied by Discovery Labs (or not previously developed by DSM for Discovery Labs) will be developed by DSM, at Discovery Labs expense, according to DSM's standard rates for development.

10.4 Reference Standards. Reference standards required for API and key components of the Product which are readily available through the U.S. Pharmacopaeia shall be provided by DSM. If such reference standards are not readily available or must be made to order, they shall be obtained at Discovery Labs expense, including any re-certifications thereof.

10.5 Stability Studies. Discovery Labs shall be responsible for conducting stability studies unless otherwise agreed by the Parties in writing. Upon Discovery Labs request and mutual written agreement of the Parties, DSM may provide stability studies at DSM's standard rates. Upon divestment of any Products hereunder, or upon termination of this Agreement, Discovery Labs shall arrange for transfer of any pending stability studies within **[***]** divestment (or the Interim Supply Period if applicable) or termination, or, alternatively, Discovery Labs and DSM shall agree on any further costs, terms and conditions, to complete the stability studies at the DSM facility.

ARTICLE 11: TERM; TERMINATION

11.1 Term. Unless sooner terminated pursuant to the terms hereof or otherwise extended through mutual written agreement of the Parties, the term of this Agreement shall commence on the Effective Date and shall continue in force and effect until the later of (i) December 31, 2015 or (ii) the expiration of all Product Terms set forth in Product Addendums entered into hereunder.

11.2 Termination by Mutual Agreement. This Agreement may be terminated at any time upon mutual written agreement between the Parties.

11.3 Termination for Default. This Agreement may be terminated by either Party in the event of the material breach or default by the other Party of the terms and conditions hereof, provided that the non-breaching 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 amounts hereunder when due); or (other than with respect to Discovery Labs failure to pay any amounts hereunder when due) 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 so to work diligently and to cure such breach within the additional time set forth above, then the other Party may either suspend the Agreement indefinitely or terminate the Agreement. Termination of this Agreement pursuant to this Section 11.3 shall not affect any other rights or remedies which may be available to the non-defaulting Party.

11.4 Bankruptcy; Insolvency. Either Party may terminate this Agreement upon the occurrence of either of the following:

11.4.1 The entry of a decree or order for relief by a court having jurisdiction in respect of the other Party in an involuntary case under the Federal Bankruptcy Code, as now constituted or hereafter amended, or under 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 sixty (60) consecutive days; or

11.4.2 The filing by the other 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.

11.5 Termination for Zero Forecasts or Non-Approval. This Agreement may also be terminated by DSM in the event of **[***]** of zero forecasts by Discovery Labs, in accordance with Section 6.7 above. Alternatively, Discovery Labs may immediately terminate this Agreement or the applicable Product Addendum without penalty (but otherwise subject to the provisions of this section 11) if (a) any Product is denied approval by the FDA, (b) FDA approval to market the Product is withdrawn, or (c) if any FDA or other regulatory action or inaction causes Discovery Labs, in its sole discretion, to discontinue the sale or marketing of such Product.

11.6 Expiration; Termination; Consequences. Upon termination of this Agreement upon notice by either party prior to the expiration date, (except in the case of material breach by DSM) DSM shall manufacture and ship, and Discovery Labs shall purchase in accordance with the provisions hereof, any and all quantities of Product ordered by Discovery Labs via Purchase Order hereunder prior to the date on which such notice is effective (or Discovery Labs may elect to otherwise pay for such quantities without requiring DSM to manufacture and ship such quantities); and DSM shall return to Discovery Labs all unused Active Pharmaceutical Ingredients in DSM's possession which have been provided by Discovery Labs hereunder. In addition, upon expiration or termination of this Agreement, (i) the Parties shall promptly agree on a procedure which allows Discovery Labs to possess any equipment located at DSM's facility that is owned by Discovery Labs (with Discovery Labs paying all reasonable costs to access and remove such equipment, including DSM's facility restoration costs), or, if the parties so agree, (ii) DSM shall purchase such equipment from Discovery Labs by paying Discovery Labs the book value thereof as depreciated on a straight-line basis based on average years of usable life.

11.7 For any termination or expiration pursuant to section 11, 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 twelve (12) months following the date of termination or expiration of this Agreement.

11.8 Purchase of Remaining Inventories. In addition, upon expiration or termination of this Agreement (except in the case of material breach by DSM), Discovery Labs shall purchase from DSM (i) **[***]**, (ii) all work-in-progress for the Product at DSM's cost, and (iii) all other finished Product then in DSM's possession; and (iv) Discovery Labs shall compensate DSM for (a) all other uncancellable commitments to Third Parties made by DSM to satisfy existing Purchase Orders, and (b) all Obsolete Stock for which Discovery Labs has not reimbursed DSM in accordance with Section 6.9. Notwithstanding the foregoing, if any cancellation penalty amount is less than an actual expense for such commitment (including restocking fees for returnable materials), Discovery Labs shall be required to reimburse DSM solely for the amount of the cancellation penalty rather than for the applicable expense.

11.9 Upon expiration or termination of this Agreement, the obligations of confidentiality and restrictions on use of Confidential Information under Article 14 hereof shall survive for the period provided therein.

ARTICLE 12: CLAIMS

12.1 Claims.

12.1.1 In the event that any of the Product delivered to Discovery Labs' designated carrier by DSM shall, upon visual inspection, fail to conform with the Product Specifications, Discovery Labs shall reject such Product by giving written notice to DSM within **[***]** after Discovery Labs receipt of such Product and all associated quality assurance documents, including, without limitation, the certificate of analysis. Discovery Labs shall give notice of any defect, latent or otherwise, not discovered during the incoming visual inspection promptly after its discovery.

12.1.2 For any claim relating to the container or container closure system for Products utilizing glass containers packaged by DSM, Discovery Labs shall make the subject vials available to DSM for analysis.

12.1.3 Claims relating to alleged mistakes with respect to invoiced quantities or pricing shall be provided to the other party within **[***]** following the date of the original invoice stating such quantities or prices, after which period such claims shall be deemed to have been waived.

12.14 Any notice given hereunder shall specify the manner in which the Product fails to meet such warranty or the Specifications. If it is determined by agreement of the Parties (or in the absence of agreement of the Parties, by a mutually acceptable independent laboratory or consultant whose fees shall be paid by the non-prevailing Party), that the nonconformity is due to damage to the Product caused by Discovery Labs or its agents, then DSM shall have no liability to Discovery Labs with respect thereto. If the nonconformity is otherwise caused by DSM's breach of this Agreement, negligence or willful misconduct, then DSM shall credit Discovery Labs' account for the price invoiced for such nonconforming Product as well as the Acquisition Costs (or, if applicable, pre-agreed designated costs) of the Active Pharmaceutical Ingredients and any other materials supplied by Discovery Labs to DSM hereunder which were used in such nonconforming Product, together with all out-of-pocket expenses (including, without limitation, all shipping charges) associated with the purchase and return of the Product; provided, however, that should the foregoing occur in conjunction with the termination or expiration of this agreement, DSM shall give Discovery Labs a refund, rather than a credit.

12.1.5 If payment therefore has previously been made by Discovery Labs, DSM shall, at Discovery Labs' option, (i) apply such credit against future orders; (ii) offset the amount thereof against other amounts then due DSM hereunder; or (iii) replace such nonconforming Product with conforming Product at no additional cost to Discovery Labs.

12.2 Waiver of Claims. CLAIMS ARISING HEREUNDER SHALL BE DEEMED TO HAVE BEEN WAIVED BY Discovery Labs IF NOT BROUGHT WITHIN **[***]**, EXCEPT FOR CLAIMS RELATING TO LATENT PRODUCT DEFECTS WHICH COULD NOT REASONABLY HAVE BEEN DISCOVERED WITHIN **[***]**. AFTER SUCH **[***]** PERIOD, SUCH LATENT DEFECT CLAIMS SHALL BE DEEMED WAIVED BY Discovery Labs IF NOT BROUGHT WITHIN **[***]**, BUT IN NO CASE LATER THAN **[***]**. CLAIMS RELATING TO INVOICED QUANTITIES OR PRICING SHALL BE PROVIDED TO THE OTHER PARTY WITHIN **[***]**, AFTER WHICH PERIOD SUCH CLAIMS SHALL BE DEEMED TO HAVE BEEN WAIVED.

12.3 Disposition of Nonconforming Product. In any case where Discovery Labs expects to make a claim against DSM with respect to damaged or otherwise nonconforming Product, Discovery Labs shall not dispose of such Product without written authorization and instructions of DSM either to dispose of the Product or to return the Product to DSM.

12.4 Product Holds/Rejects. DSM will notify Discovery Labs of Product holds and/or rejects that may have an impact on the manufacturing process and that may require Discovery Labs approval prior to resolution.

ARTICLE 13: INDEMNIFICATION OF THIRD PARTY CLAIMS

13.1 Indemnification by Discovery Labs. 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) 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; (b) 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 pursuant to Section 2.5 above; (c) 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 (d) any act or omission of negligence, gross negligence, or willful misconduct by Discovery Labs or its respective directors, officers, employees, agents, or representatives.

13.2 Indemnification by DSM. 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 of illness, injury or death caused by the use of any Product manufactured by DSM hereunder which does not conform to the Product Specifications; (b) any proceeding instituted by or on behalf of a Third Party based upon a claim that the manufacture of the Product infringes a United States patent or any other proprietary rights (except for such claims as are subject to indemnity by Discovery Labs pursuant to Section 13.1, 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.

13.3 Indemnification Procedures. A Party which intends to claim indemnification under this Article 13 (the "Indemnitee") 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; and the Indemnitor shall not compromise or settle any matter without the written consent of the Indemnitee, which consent shall not be unreasonably withheld or delayed. In no event shall the Indemnitee compromise or settle any such matter without the prior written consent of the Indemnitor, which consent shall not be unreasonably withheld or delayed; nor shall the non-consenting Indemnitor 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.

13.4 Survival of Indemnification Obligations. The provisions of this Article 13 shall survive the expiration or termination of this Agreement.

ARTICLE 14: CONFIDENTIALITY

14.1 During the term of this Agreement and for a period of **[***]**, each of Discovery Labs and DSM agrees not to publish, disclose or use for any purpose other than its performance hereunder, any information disclosed by the other Party which is DSM Intellectual Property or Discovery Labs' Intellectual Property (as both terms are defined below), respectively, or which is commonly regarded as proprietary or confidential ("Confidential Information"), including, without limitation, information stored on audio or video tapes and disks, or information or knowledge visually acquired by or generated by Discovery Labs or DSM personnel in the form of written notes and memoranda memorializing information or knowledge acquired visually, aurally or orally in the course of either Party's performance hereunder.

14.2 Each Party (the "Receiving Party") shall limit disclosure of Confidential Information received hereunder from the disclosing party (the "Disclosing Party") to only those officers and employees of the Receiving Party (or its Affiliates') who are directly concerned with the performance of this Agreement. Each Party shall advise such officers or employees upon disclosure of any Confidential Information to them of the confidential nature of the Confidential Information and the terms and conditions of this Article 14, and shall use all reasonable safeguards to prevent unauthorized disclosure of the Confidential Information by such officers and employees.

14.3 Both Parties agree that the following shall not be considered Confidential Information subject to this Agreement:

14.3.1 information that is in the public domain by publication or otherwise, provided that such publication is not in violation of this Agreement or any other confidentiality agreement;

14.3.2 information that the Receiving Party can establish in writing was in the Receiving Party's possession prior to the time of disclosure by the Disclosing Party and was not acquired, directly or indirectly, from the Disclosing Party;

14.3.3 information that the Receiving Party lawfully receives from a Third Party; provided, however, that such Third Party was not obligated to hold such information in confidence;

14.3.4 information that, prior to the Disclosing Party's disclosure thereof, was independently developed by the Receiving Party without reference to any Confidential Information as established by appropriate documentation; and

14.4 Information that the Receiving Party is compelled to disclose by a court, administrative agency, or other tribunal shall be considered Confidential Information, but may be disclosed as compelled; provided however, that in such case the Receiving Party shall immediately give as much advance notice as feasible to the Disclosing Party to enable the Disclosing Party to exercise its legal rights to prevent and/or limit such disclosure. In any event, the Receiving Party shall disclose only that portion of the Confidential Information that, in the opinion of the Receiving Party's legal counsel, is legally required to be disclosed and will exercise reasonable best efforts to ensure that any such information so disclosed will be accorded confidential treatment by said court, administrative agency or tribunal.

14.5 All Confidential Information shall remain the property of the Disclosing Party. Upon the termination of this Agreement, or at any time upon the request of the other Party, the Receiving Party shall immediately return or destroy any Confidential Information in the Receiving Party's possession, custody or control, except that the Receiving Party may keep one (1) copy for archival purposes. The Disclosing Party's failure to request the return of Confidential Information shall not relieve the Receiving Party of its confidentiality obligations under this Agreement.

14.6 Each Party acknowledges and expressly agrees that the remedy at law for any breach by it of the terms of this Article 14 shall be inadequate and that the full amount of damages which would result from such breach are not readily susceptible to being measured in monetary terms. Accordingly, in the event of a breach or threatened breach by either Party of this Article 14, the other Party shall be entitled to immediate injunctive relief prohibiting any such breach and requiring the immediate return of all Confidential Information. The remedies set forth in this Section 14.6 shall be in addition to any other remedies available for any such breach or threatened breach, including the recovery of damages from the breaching Party.

14.7 The terms and conditions of this Agreement, but not the fact of its existence, shall constitute Confidential Information of Discovery Labs, except that either Party may disclose such terms and conditions to its Affiliates in accordance with Section 14.2 hereof.

14.8 Neither Party will make any public announcement of any information regarding this Agreement or any activities hereunder without the prior written approval of the other Party; provided, however, that each Party may disclose (i) if required by applicable law, the general existence of this Agreement, and any non-confidential information required by applicable law (including information provided in connection with required public regulatory filings and public securities filings), and (ii) any other information that has been approved in writing for disclosure by the other Party. Further, each Party or their parent company may announce the signing of this Agreement in their quarterly results release without prior approval. Any press release, publicity or other form of public written disclosure related to this Agreement prepared by one Party shall be require approval of the other Party and shall be submitted to the other Party prior to release for approval, which approval shall not be unreasonably withheld or delayed by such other Party. The Parties acknowledge that Discovery Labs intends to file in its public securities filings (e.g., 10-Q or 8-K) a description of this Agreement and a copy of this Agreement. DSM agrees that Discovery Labs may submit a description and 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 by applicable regulatory authorities to require disclosure.

14.9 INFORMATION PROVIDED BY DISCOVERY LABS RELATED TO MANUFACTURING AND FABRICATING PROCESSES AND RELATED ANALYTICAL METHODOLOGIES OF DISCOVERY LABS SHALL BE CONSIDERED TRADE SECRETS OF DISCOVERY LABS. PROVIDED THAT SUCH INFORMATION IS CLEARLY IDENTIFIED AS A TRADE SECRET BY DISCOVERY LABS, THE CONFIDENTIALITY OBLIGATIONS WITH RESPECT TO SUCH INFORMATION SHALL SURVIVE THE EXPIRATION OR TERMINATION OF THIS AGREEMENT, INCLUDING THE TIME LIMITATIONS AS SET FORTH IN SECTION 14.1. CONFIDENTIALITY OBLIGATIONS WITH RESPECT TO SUCH TRADE SECRETS SHALL CONTINUE FOR AS LONG AS SUCH INFORMATION REMAINS A TRADE SECRET UNDER APPLICABLE LAW.

ARTICLE 15: INTELLECTUAL PROPERTY

15.1 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, (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 related to Discovery Labs' Intellectual Property 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 15.2(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").

15.2 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 15.2(a) and 15.2(b) to the extent severable from the Discovery Labs' Intellectual Property described in Paragraphs 15.1(a) and (b), and (c).

15.3 [Intentionally Left Blank].

15.4 With regard to any Invention described in Paragraph 15.2(c) above, that is derived in connection with the work performed under this Agreement, Discovery Labs shall have a non-exclusive, worldwide, royalty free, license to use such Invention to the extent necessary to assist Discovery Labs in its performance hereunder. Discovery Labs shall acquire no other right, title or interest in the DSM Intellectual Property as a result of its performance hereunder.

15.5 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 Paragraphs 15.1 through 15.4 , 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.

15.6 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.

15.7 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.

15.8 Except as expressly stated in this Agreement, no Intellectual Property rights of any kind or nature are conveyed by this Agreement and 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.

ARTICLE 16: FORCE MAJEURE

16.1 Effects of Force Majeure. Neither Party shall be held liable or responsible for failure or delay in fulfilling or performing any of its obligations under this Agreement in case such failure or delay is due to 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, breakage or failure of machinery or apparatus, national defense requirements, or supplier strike, lockout or injunction (a "Force Majeure Event"). Such excuse shall continue as long as the Force Majeure Event continues, provided, however, that Discovery Labs may cancel without penalty any and all Purchase Orders in the event DSM is unable to fulfill an outstanding Purchase Order within sixty (60) days of its scheduled delivery date due to a Force Majeure Event. Upon cessation of such Force Majeure Event, such Party shall promptly resume performance on all Purchase Orders which have not been terminated. Upon resolution of a Force Majeure Event, the Parties shall negotiate in good faith any adjustments to Minimum Purchase Commitment terms, Minimum Contract Quantities, or other agreement minimums or expectations to apply to the Contract Year during which the Force Majeure Event occurred.

16.2 Notice of Force Majeure Event. In the event either Party is delayed or rendered unable to perform due to a Force Majeure Event, the affected Party shall give notice thereof and its expected duration to the other Party promptly after the occurrence of the force majeure event; and thereafter, the obligations of the affected Party will be suspended during the continuance of the Force Majeure Event. The affected Party shall take commercially reasonable steps to remedy the Force Majeure Event with all reasonable dispatch, but such obligation shall not require the settlement of strikes or labor controversies on terms unfavorable to the affected Party.

ARTICLE 17: LEGAL COMPLIANCE; AUTHORIZATION

17.1 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 FD&C Act.

17.2 Authorization.

17.2.1 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.

17.2.2 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.

ARTICLE 18: USE OF NAMES

18.1 Use of Names. Except as expressly provided or contemplated hereunder and except as otherwise required by applicable law, no right is granted pursuant to this Agreement to either Party to use in any manner the trademarks or name of the other Party, or any other trade name, service mark, or trademark owned by or licensed to the other Party in connection with the performance of this Agreement. Notwithstanding the above, as may be required by applicable law, Discovery Labs, DSM and their Affiliates shall be permitted to use the other Party's name and to disclose the existence and terms of this Agreement in connection with securities or other public filings pursuant to section 14.8.

ARTICLE 19: DISPUTE RESOLUTION; VENUE

19.1 Arbitration. 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 **[***]**. In the event the designated officers are not able to resolve such dispute within such **[***]**, 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 Article 14.

19.2 Venue. The arbitration shall take place in a mutually agreeable location, but if the Parties cannot agree as to the location, the arbitration shall take place in New York. The arbitrators shall apply the law of the State of New York without regard to conflicts of law provisions.

ARTICLE 20: MISCELLANEOUS

20.1 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 **[***]** 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.

20.2 Independent Contractors. The relationship between Discovery Labs and DSM is that of independent contractors and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between Discovery Labs and DSM. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

20.3 Assistance from Discovery Labs. 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 any information, documentation and data relating to product safety and information, documentation and data, including NDA and/or other Regulatory Documentation numbers, NDC codes, etc., necessary for DSM to drug list the product) which is necessary or appropriate for DSM's performance hereunder. If requested by DSM to provide support or information, Discovery Labs shall provide such support or information (or an explanation of the legitimate reason for any delay and a projected date by which such support or information will be provided) within five (5) business days of DSM's request. In the event Discovery Labs is to review or approve any information, documentation, data or samples prepared or supplied by or on behalf of DSM, it shall in good-faith endeavor to complete such review and approval process within five (5) business days.

20.4 Assignment; Subcontractors. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party, which consent shall not unreasonably be withheld provided, however, that either party may assign this Agreement to any of its Affiliates or to the purchaser of all or substantially all of its assets, or to its successor entity or acquirer in the event of a merger, consolidation or change in control of such party without the consent, written or otherwise, of the other party. Any purported assignment in violation of the preceding sentences shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either Party of responsibility for the performance of any obligation which accrued prior to the effective date of such assignment. DSM may, with Discovery Labs' prior written consent, utilize subcontractors to perform any part of this Agreement, provided that said subcontractors shall be subject to all relevant and material obligations incurred hereunder, including, without limitation, the obligations with respect to confidentiality and intellectual property as set forth in sections 14 and 15. DSM shall remain primarily responsible for all services performed by any subcontractor under this Agreement and shall be responsible to manage the activities of any such subcontractor.

20.5 Continuing Obligations. Termination, assignment or expiration of this Agreement shall not relieve either Party from full performance of any obligations incurred prior thereto.

20.6 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.

20.7 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.

20.8 Headings. The headings in this Agreement are for convenience of reference only and shall not affect its interpretation.

20.9 Construction. This Agreement has been jointly prepared on the basis of the mutual understanding of the Parties and shall not be construed against either Party by reason of such Party's being the drafter hereof or thereof.

20.10 Annexes, Schedules and Attachments. Any and all annexes, schedules and attachments referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

20.11 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

20.12 Counterparts. This Agreement and any amendment or supplement hereto may be executed in any number of counterparts and any Party hereto may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. The execution of this Agreement and any such amendment or supplement by any Party hereto will not become effective until counterparts hereof have been executed by both Parties hereto.

20.13 Governing Law; Entire Agreement. The validity, interpretation and performance of this Agreement shall be governed and construed in accordance with the laws of the State of New York without regard to the conflicts of laws provisions thereof. This Agreement constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement. No terms, conditions, understanding, or agreement purporting to modify or vary the terms of this Agreement shall be binding unless hereafter made in writing and signed by the Party to be bound. No modification to this Agreement shall be effected by the acknowledgment or acceptance of any Purchase Order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein.

20.14 Annexes. The following annexes are attached hereto and incorporated herein by reference:

ANNEX 1:	Product Addendum for each Product
ANNEX 2:	Capital Equipment
ANNEX 3:	Additional Regulatory Support

20.15 FDA Debarment Certification. DSM represents and warrants that it will not knowingly employ, contract with or retain any person directly or indirectly to perform services under this Agreement, if such person is known by DSM to be debarred by the FDA under 21 USC 335a(k) of the FD&C Act.

[Signatures on following page]

[*] Denotes that confidential treatment of redacted portions has been requested.**

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the day and year first above written.

DSM Pharmaceuticals Inc. (“DSM”)

By: _____
[*]**

Discovery Laboratories, Inc. (“Discovery Labs”)

By: /s/ John Tattory
Name: John Tattory
Title: Vice President, Finance

[*] Denotes that confidential treatment of redacted portions has been requested.**

ANNEX 1:

**PRODUCT SPECIFICATIONS, PRICING,
AND OTHER INFORMATION**

SURFAXIN® (lucinactant) Intratracheal Suspension – Liquid

[*]**

[*] Denotes that confidential treatment of redacted portions has been requested.**

ANNEX 2: CAPITAL / EQUIPMENT

[*]**

[*] Denotes that confidential treatment of redacted portions has been requested.**

ANNEX 3: REGULATORY SUPPORT

Discovery Labs is responsible for submitting the registration package for regulatory agency approval within a mutually agreed time from receipt of the package from DSM (data only package). DSM will provide standard regulatory support for Product to include:

- Annual product review (APR)
- Maintenance of site Drug Master Files as required to support Product production facilities
- Regulatory agency hosting for pre-approval inspections (PAI)

Discovery Labs is financially responsible for all non-standard regulatory support that DSM may provide upon Discovery Labs request.

Exhibit 31.1

CERTIFICATIONS

I, John G. Cooper, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 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 June 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: August 8, 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.