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

# **FORM 10-Q**

#### QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2014

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from

to

Commission file number 000-26422

# DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

**Delaware** 

94-3171943

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

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

(215) 488-9300

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES 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 April 30, 2014, 85,052,281 shares of the registrant's common stock, par value \$0.001 per share, were outstanding.

# PART I - FINANCIAL INFORMATION

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

#### FORWARD-LOOKING STATEMENTS

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

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

- the risk that we will require in the near term, but may be unable to secure, significant additional capital to continue our operations, fund our debt service and support our research and development activities, including expensive and time-consuming clinical trials, until such time, if ever, that our revenues from all sources are sufficient to offset our cash outflows. To the extent that we raise such capital through additional financings, such additional financings could result in equity dilution;
- the risk that, if we fail to successfully commercialize SURFAXIN and if we are unable to achieve revenues over the next several years that are consistent with our expectations, it may be more difficult to secure the additional capital we will require when needed, if at all, whether from strategic alliances or other sources, to continue our commercial and medical affairs activities, as well as our research and development programs and our operations would be impaired, which ultimately could have a material adverse effect on our business, financial condition and results of operations;
- risks relating to the ability of our sales and marketing organization to effectively introduce SURFAXIN in the United States (U.S.) and, if approved, our other product candidates, in a timely manner, if at all; and that we may not succeed in developing sufficient market awareness of our products or that our product candidates may not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;

- risks relating to our ability to timely modify our business strategy to respond to changing circumstances, assumptions and forecasts, and otherwise as
  needed to manage growth effectively and respond to developments in our commercial operations and research and development activities, as well as
  our business, our industry and other factors;
- the risk that the initial and later phases of our AEROSURF phase 2 clinical program may be interrupted, delayed, or fail, which will harm our business;
- the risk that we and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;
- risks relating to the transfer of our manufacturing technology to contract manufacturing organizations (CMOs) and assemblers;
- risks relating to our and our CMOs' ability to manufacture our KL4 surfactant, in liquid and lyophilized dosage forms, which 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;
- risks relating to our and our CMOs' ability to develop and manufacture combination drug/device products based on our CAG technology, for
  preclinical and clinical studies of our product candidates and, if approved, for commercialization;
- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems in manufacturing our KL<sub>4</sub> surfactant drug products and the APIs used in the manufacture of our drug products, CAG devices and other materials on a timely basis or in an amount sufficient to support our needs;
- the risk that we may not succeed in implementing our long-term manufacturing strategy to assure continuity of SURFAXIN commercial drug
  product supply, which could expose us to risks that may affect our ability to maintain sufficient supplies of SURFAXIN commercial drug product;
- the risk that we may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us in markets outside
  the U.S. with the development of our KL4 surfactant pipeline products, beginning with AEROSURF, including development of our lyophilized KL4
  surfactant, and, if approved, commercialization of AEROSURF in markets outside the U.S.; support the commercialization of SURFAXIN in
  countries where regulatory approval is facilitated by the information contained in the SURFAXIN new drug application (NDA) approved by the
  FDA; and potentially support the development and, if approved, commercialization, of our other pipeline products;
- risks relating to our plans potentially to secure marketing and distribution capabilities in certain markets through third-party strategic alliances
  and/or marketing alliances and/or distribution arrangements, that could require us to give up rights to our drug products, drug product candidates and
  drug delivery technologies;
- risks relating to our pledge of substantially all of our assets to secure our obligations under our loan facility (Deerfield Loan) with affiliates of Deerfield Management Company, L.P., which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investment; and
- other risks and uncertainties as detailed in "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 17, 2014, and our other filings with the SEC and any amendments thereto, and in the documents incorporated by reference in this report.

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

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

Trademark Notice

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

#### PART I - FINANCIAL INFORMATION

# ITEM 1. FINANCIAL STATEMENTS

# DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets
(in thousands, except per share data)

(in thousands, except per share data)				
		March 31, 2014		cember 31, 2013
A CONTINU	(U	naudited)		
ASSETS				
Current Assets:	\$	75.042	\$	86,283
Cash and cash equivalents Accounts receivable	Ф	75,942	Ф	67
Inventory, net		173		112
Prepaid expenses and other current assets		702		777
Total current assets	_	76,817	_	87,239
				1,656
Property and equipment, net Restricted cash		2,007 325		325
Other assets		349		97
	ď		¢	89,317
Total assets	\$	79,498	\$	89,317
LIABILITIES & STOCKHOLDERS' EQUITY				
Current Liabilities:			_	
Accounts payable	\$	2,578	\$	1,433
Accrued expenses		3,726		4,785
Deferred revenue		85		139
Common stock warrant liability		4,672		5,425
Equipment loans, current portion		74		73
Total current liabilities		11,135		11,855
Long-term debt, \$30,000 net of discount of \$11,207 at March 31, 2014 and \$11,646 at December 31, 2013		18,793		18,354
Equipment loans, non-current portion		49		69
Other liabilities		714		538
Total liabilities		30,691		30,816
Stockholders' Equity:				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding		_		_
Common stock, \$0.001 par value; 150,000,000 shares authorized; 85,073,173 and 84,659,111 shares issued at March 31, 2014 and December 31, 2013, respectively; 85,052,281 and 84,638,219 shares outstanding at March 31, 2014				
and December 31, 2013, respectively		85		85
Additional paid-in capital		543,202		541,420
Accumulated deficit		(491,426)		(479,950)
Treasury stock (at cost); 20,892 shares		(3,054)		(3,054)
Total stockholders' equity		48,807		58,501
Total liabilities & stockholders' equity	\$	79,498	\$	89,317

See notes to consolidated financial statements.

# DISCOVERY LABORATORIES, INC. AND SUBSIDIARY Consolidated Statements of Operations

(Unaudited)

(in thousands, except per share data)

(in thousands, except per share data)	Tl	Three Months Ended March 31,	
	20	14	2013
Revenues:			
Product sales	\$	28	\$ -
Grant revenue		3	72
		31	72
Expenses:			
Cost of product sales		781	_
Research and development		5,590	8,472
Selling, general and administrative		4,423	4,220
		10,794	12,692
Operating loss		(10,763)	(12,620)
Change in fair value of common stock warrant liability		378	162
Other income / (expense):			
Interest and other income		2	1
Interest and other expense		(1,093)	(178)
Other income / (expense), net		(1,091)	(177)
Net loss	<u>\$</u>	(11,476) S	\$ (12,635)
Net loss per common share – Basic and diluted	\$	(0.14)	\$ (0.29)
Weighted-average number of common shares outstanding – basic and diluted		84,728	43,657

See notes to consolidated financial statements.

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

(in thousands)

	5	Three Montl March	
	2	014	2013
Cash flows from operating activities:	ф	(11 450)	ф (10 CDE)
Net loss	\$	(11,476)	\$ (12,635)
Adjustments to reconcile net loss to net cash used in operating activities:  Depreciation and amortization		149	197
Provision for excess inventory		766	197
Stock-based compensation and 401(k) Plan employer match		954	612
Fair value adjustment of common stock warrants		(378)	(162)
Amortization of discount on long-term debt		439	59
Changes in:		733	33
Inventory		(1,083)	195
Accounts receivable		67	_
Prepaid expenses and other current assets		75	98
Accounts payable		1,145	659
Accrued expenses		(1,059)	814
Deferred revenue		(54)	_
Other assets		_	(111)
Other liabilities		176	39
Net cash used in operating activities		(10,279)	(10,235)
Cash flows from investing activities:			
Purchase of property and equipment		(497)	(120)
Net cash used in investing activities		(497)	(120)
Cash flows from financing activities:			
Proceeds from issuance of long-term debt, net of expenses		_	9,850
Proceeds from exercise of common stock options		31	1
Proceeds from exercise of common stock warrants		423	_
Repayment of equipment loans		(19)	(18)
Net cash provided by financing activities		435	9,833
Net decrease in cash and cash equivalents		(10,341)	(522)
Cash and cash equivalents – beginning of period		86,283	26,892
Cash and cash equivalents – end of period	\$	75,942	\$ 26,370
Supplementary disclosure of cash flows information:			
Interest paid	\$	649	\$ 116
	Ψ	0.0	
See notes to consolidated financial statements.			
3			

#### 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 (KL4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of our aerosolized KL4 surfactant. We believe that our proprietary technologies may make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

We are initially focused on improving the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants. RDS is the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU) and can result in long-term respiratory problems, developmental delay and death. Our first KL4 surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL4 surfactant in liquid form, and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States (U.S.). SURFAXIN has been commercially available in the U.S. since November 2013.

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

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

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

To support the commercial introduction of SURFAXIN in the U.S. and our other KL4 surfactant pipeline products, if approved, we have established our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL4 surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL4 surfactant.

In addition, we recognize that our commercial and medical affairs team could potentially support introductions of other synergistic pipeline products, including products owned or developed by third parties for the NICU/PICU. To that end, we would consider potential transactions focused on securing commercial rights to such synergistic products, including in the form of product acquisitions, in-licensing agreements or distribution, marketing or comarketing arrangements.

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

We also have developed a disposable aerosol-conducting airway connector for infants that is intended to simplify the delivery of aerosolized medications (including our aerosolized KL4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support. This device introduces aerosolized medications directly at the patient interface and minimizes the number of connections in the ventilator circuit. We have registered this device in the U.S. as a Class I, exempt medical device under the name AFECTAIR® and it is currently commercially available in the U.S.

#### Note 2 - Liquidity Risks and Management's Plans

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

As of March 31, 2014, we had cash and cash equivalents of \$75.9 million and long-term debt of \$30 million (\$18.8 million net of discount) under our Deerfield Loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 7 – "Deerfield Loan"). Before any additional financings, including under our ATM Program (see, Note 11, "At-the-Market Program (ATM Program)," to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2013 (2013 Form 10-K)), we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the third quarter of 2015.

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

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

As of March 31, 2014, we had outstanding warrants to purchase approximately 14.5 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, warrants to purchase 7 million shares were issued to Deerfield in connection with the Deerfield Loan at an exercise price of \$2.81 per share. The Deerfield Warrants may be exercised for cash or on a cashless basis. In lieu of paying cash upon exercise, the holders also may elect to reduce the principal amount of the Deerfield Loan in an amount sufficient to satisfy the exercise price of the Deerfield Warrants. In addition to the Deerfield Warrants, we have outstanding five-year warrants issued in February 2011 to purchase approximately 4.6 million shares of common stock that contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. These warrants currently have an exercise price of \$1.50 per share. 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 would make exercise of outstanding warrants likely, that holders of the Deerfield Warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise

As of March 31, 2014, 150 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, and approximately 42.1 million shares of common stock were available for issuance and not otherwise reserved.

Although we currently believe that we will be able to successfully execute our business strategy, there can be no assurance that our AEROSURF development program will be successful within our anticipated time frame, if at all, that we will succeed in obtaining the necessary regulatory approvals in the U.S. and other markets, that any approved product, including SURFAXIN, will be commercially viable, that the ATM Program will be available when needed, if at all, or that we will be able to obtain additional capital when needed on acceptable terms, if at all, that we will be successful. We will require significant additional capital to satisfy debt obligations and sustain operations, and to complete the development and, if they are approved, support the commercial introduction of our products. Failure to secure the necessary additional capital would have a material adverse effect on our business, financial condition and results of operations. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

#### 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 consolidated financial statements. In the opinion of management, all adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. There have been no changes to our critical accounting policies since December 31, 2013. For a discussion of our accounting policies, *see*, the consolidated financial statements and notes thereto in our 2013 Form 10-K. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

#### **Inventory**

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

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

#### Accrued Severance and Retention Costs

A liability for employee severance and retention benefits is recognized when (1) management has committed to a plan of termination; (2) the plan provides sufficient details, such as the employees affected, amounts to be paid, and expected dates of termination and payment; (3) it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn; and (4) the plan has been communicated to employees. The cost of such benefits are accrued over the remaining service period.

In September 2013, we implemented an employee severance and retention plan for employees at our manufacturing facility in Totowa, NJ ("Totowa Facility") to minimize employee turnover and encourage employees to remain with us through any potential plant closing. The plan provides for severance for non-union employees and retention bonuses for management. If we succeed in our efforts to secure longer-term utilization of the Totowa Facility, the severance plan and retention bonuses will remain in effect. The total cash amount expected to be paid for severance and retention under this plan through June 2016, assuming a June 2015 plant closing, is approximately \$1.1 million. The plan-related expense incurred for the quarter ended March 31, 2014 is \$0.1 million and is included in research and development expense. The related accrued liability is \$0.2 million as of March 31, 2014.

In addition, at the Totowa Facility, there are 14 employees who are subject to a collective bargaining agreement under which they would be eligible to receive severance payments if the Totowa Facility were closed. The plan-related expense incurred for the quarter ended March 31, 2014 is \$33,000 and is included in research and development expense. The related accrued liability is \$0.4 million as of March 31, 2014.

#### **Product Sales**

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

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

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

- · Chargebacks. Chargebacks are discounts that occur when contracted customers purchase directly from our specialty distributor. Contracted customers, which currently consist primarily of member hospitals of Group Purchasing Organizations, generally purchase the product at a discounted price. Our specialty distributor, in turn, charges back the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the customer. The allowance for specialty distributor chargebacks is based on known sales to contracted customers.
- Sales discounts: Sales discounts are offered to certain contracted customers based upon a customer's historical volume of surfactant product
  purchases. Customers must enter into a Letter of Participation (LOP) with us to receive sales discounts. Sales discounts are periodically adjusted on a
  prospective basis based upon the customer's purchases of SURFAXIN, as provided in the LOP. The allowance for sales discounts is based on known
  sales to contracted customers.
- · Specialty distributor deductions. Our specialty distributor is offered various forms of consideration including allowances, service fees and prompt payment discounts. Specialty distributor allowances and service fees are provided in our contractual agreement and are generally a percentage of the purchase price paid by the specialty distributor. The specialty distributor is offered a prompt pay discount for payment within a specified period.
- Returns. Sales of our products are not subject to a general right of return; however, we will accept product that is damaged or defective when shipped
  or for expired product up to six months subsequent to its expiry date. Product that has been administered to patients is no longer subject to any right
  of return.

#### Research and development expense

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

#### Net loss per common share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. For the quarters ended March 31, 2014 and 2013, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 21.3 million and 15.8 million shares, respectively.

In accordance with Accounting Standards Codification (ASC) Topic 260, "Earnings per Share," when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of certain warrants classified as derivative liabilities results in an adjustment to the net loss; and the dilutive impact of the assumed exercise of the warrants results in an adjustment to the weighted average common shares outstanding. We utilize the treasury stock method to calculate the dilutive impact of the assumed exercise of the warrants. For the quarters ended March 31, 2014 and 2013, the effect of the adjustments for all warrants classified as derivative liabilities was non-dilutive.

For the quarters ended March 31, 2014 and 2013, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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

#### Recent accounting pronouncements

There were no new accounting pronouncements issued during the three months ended March 31, 2014 that are expected to have a material impact on the Company's financial position, operating results or disclosures.

#### Note 4 - Fair Value of Financial Instruments

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

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

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

#### Fair Value on a Recurring Basis

The tables below categorize assets and liabilities measured at fair value on a recurring basis as of March 31, 2014 and December 31, 2013:

	Fair Value	Fair value measurement using					
	March 31, 2014	Level 1	Level 2	Level 3			
Assets:							
Cash and cash equivalents	\$ 75,942	\$ 75,942	\$ - 3	-			
Certificate of Deposit	325	325	-	_			
Total Assets	\$ 76,267	\$ 76,267	\$ \$	5 –			
Liabilities:							
Common stock warrant liability	\$ 4,672	<u> </u>	<u> </u>	4,672			
	Fair Value	Fairs	alue measurement u	wing			
		raii v	alue measurement t	ising			
	December 31,	Level 1	Level 2	Level 3			
Assets:	December 31,			_			
Assets: Cash and cash equivalents	December 31,			Level 3			
	December 31, 2013	Level 1	Level 2	Level 3			
Cash and cash equivalents	December 31, 2013 \$ 86,283	Level 1 \$ 86,283	Level 2	Level 3			
Cash and cash equivalents Certificate of Deposit	December 31, 2013 \$ 86,283 325	Level 1 \$ 86,283 325	Level 2	Level 3			

The table below summarizes the activity of Level 3 inputs measured on a recurring basis for the three months ended March 31, 2014 and 2013:

(in thousands)	Fair Value Measurements of Common Stock Warrants Usin Significant Unobservable Input (Level 3)			
Balance at December 31, 2013	\$	5,425		
Exercise of warrants		(375)		
Change in fair value of common stock warrant liability		(378)		
Balance at March 31, 2014	\$	4,672		
(in thousands)	Common Stock Significant Und	easurements of Warrants Using observable Inputs vel 3)		
Balance at December 31, 2012 Change in fair value of common stock warrant liability	\$	6,305 (162)		
Balance at March 31, 2013	<u>\$</u>	6,143		

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

# Significant Unobservable Input

Assumptions of Level 3 Valuations	March 31, 2014	<b>December 31, 2013</b>
Historical Volatility	60%-62%	62% -76%
Expected Term (in years)	0.1 - 1.9	0.4 - 2.1
Risk-free interest rate	0.03% - 0.41%	0.08% - 0.44%

#### Fair Value of Long-Term Debt

At March 31, 2014, the estimated fair value of the Deerfield Loan was \$23.7 million compared to a carrying value, net of discounts, of \$18.8 million. At December 31, 2013, the estimated fair value of the Deerfield Loan was \$23.6 million compared to a carrying value, net of discounts, of \$18.4 million. The estimated fair value of the Deerfield Loan was based on discounting the future contractual cash flows to the present value. This analysis utilizes certain Level 3 unobservable inputs, including current cost of capital. Considerable judgment is required to interpret market data and to develop estimates of fair value. The estimates presented are not necessarily indicative of amounts 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 5 - Inventory

Inventory is comprised of the following for the periods presented:

(in thousands)	March 31, 2014		December 31, 2013
Inventories, current:			
Raw materials	\$ 52	\$	52
Finished goods, net of reserves	121		60
	173		112
Inventories, non-current:			
Raw materials	256		_
Total inventories, net	\$ 429	\$	112

Raw materials inventory that is not expected to be used in commercial production until more than 12 months from the balance sheet date is classified as a non-current other asset on the balance sheet. The shelf life of our raw materials is 2-5 years. Since the commercial introduction of SURFAXIN in the fourth quarter of 2013, we have made investments to increase our raw materials inventory to support future commercial production.

In addition, as of March 31, 2014, we had \$1.0 million of raw materials that were purchased prior to October 4, 2013, the date the FDA approved updated SURFAXIN product specifications, which enabled the commercial introduction of SURFAXIN. These raw materials have a carrying value of zero, as the costs to purchase this material were expensed in the period of purchase as research and development expense, and accordingly are not reflected in the inventory balances shown above. These raw materials are anticipated to be used in manufacturing development, research and development activities and in the manufacture of commercial product.

Inventory reserves as of March 31, 2014 and December 31, 2013 were \$1.3 million and \$0.5 million, respectively. Inventory reserves reflect costs of SURFAXIN finished goods inventories that are not anticipated to be recoverable through the commercial sale of the product during the initial launch period due to product expiration. These reserves ensure that the inventory carrying values do not exceed net realizable value.

#### Note 6 - Common Stock Warrant Liability

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

The form of warrant agreement for the registered warrants that we issued in our May 2009 and February 2010 public offerings generally provide that, in the event a related registration statement or an exemption from registration is not available for the issuance or resale of the warrant shares upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. Notwithstanding the availability of cashless exercise, generally accepted accounting principles (GAAP) provide that these registered warrants are deemed to be subject to potential net cash settlement and must be classified as derivative liabilities because (i) under federal securities laws, providing freely-tradable shares upon exercise of the warrants may not be within our control in all circumstances, and (ii) the warrant agreements do not expressly provide that there is no circumstance in which we may be required to effect a net cash settlement of the warrants. The accounting guidance expressly precludes an evaluation of the likelihood that cash settlement could occur. Accordingly, the May 2009 and February 2010 warrants 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 form of warrant agreement for the registered five-year warrants that we issued in the February 2011 public offering (February 2011 five-year warrants) contain anti-dilutive provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the February 2011 five-year warrants. Although by their express terms, these warrants are not subject to potential cash settlement, due to the nature of the anti-dilution provisions, these warrants have been classified as derivative liabilities and reported, at each balance sheet date, at estimated fair value determined using a trinomial pricing model.

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

								Value of Warrants In thousands)	6	
Issuance Date	W	umber of arrant Shares suable	Exercise Price		Warrant Expiration Date	Value at Issuance Date		March 31, 2014		December 31, 2013
5/1	3/2009	466,667	\$	17.25	5/13/2014	\$	3,360	\$ _	\$	-
2/2	3/2010	916,669		12.75	2/23/2015		5,701	1		6
2/2	2/2011	4,552,600		1.50	2/22/2016		8,004	4,671		5,419
								\$ 4,672	\$	5,425

During the three months ended March 31, 2014, holders of the February 2011 five-year warrants exercised warrants to purchase 282,350 shares of common stock for total proceeds of \$0.4 million. There were no February 2011 five-year warrants exercised during the three months ended March 31, 2013.

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

#### Note 7 - Deerfield Loan

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

(in thousands)	M	March 31, 2014		December 31, 2013
Note Payable	\$	30,000	\$	30,000
Unamortized discount		(11,207)		(11,646)
Long-term debt, net of discount	\$	18,793	\$	18,354

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

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

(in thousands)	Three months ended March 31,					
		2014		2013		
Cash interest expense	\$	647	\$	113		
Non-cash amortization of debt discount		439		57		
Amortization of debt costs		5		5		
Total interest expense	\$	1,091	\$	175		

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

In connection with the loan, we issued to Deerfield warrants to purchase 7.0 million shares of our common stock at an exercise price of \$2.81 per share that expire on February 13, 2019. The Deerfield warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815 "Derivatives and Hedging – Contracts in Entity's Own Equity" (ASC 815) and are classified as equity. See, Note 9, "Deerfield Loan," to the Consolidated Financial Statements in our 2013 Form 10-K.

#### Note 8 - Stock Options and Stock-Based Employee Compensation

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

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses weighted-average assumptions noted in the following table.

	March 3	March 31,			
	2014	2013			
Weighted-average expected volatility	100%	110%			
Weighted-average expected term	5.4 years	4.8 years			
Weighted-average risk-free interest rate	1.6%	0.74%			
Expected dividends	_	_			

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

(in thousands)	Three Months Ended March 31,		
	20	)14	 2013
Research & Development	\$	248	\$ 141
Selling, General & Administrative		455	215
Total	\$	703	\$ 356

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

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

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

#### **OVERVIEW**

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

We are initially focused on improving the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants. RDS is the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU) and can result in long-term respiratory problems, developmental delay and death. Our first KL4 surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL4 surfactant in liquid form, and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States (U.S.). SURFAXIN has been commercially available in the U.S. since November 2013.

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

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

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

To support the commercial introduction of SURFAXIN in the U.S. and our other KL4 surfactant pipeline products, if approved, we have established our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL4 surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL4 surfactant.

In addition, we recognize that our commercial and medical affairs team could potentially support introductions of other synergistic pipeline products, including products owned or developed by third parties for the NICU/PICU. To that end, we would consider potential transactions focused on securing commercial rights to such synergistic products, including in the form of product acquisitions, in-licensing agreements or distribution, marketing or comarketing arrangements.

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

We also have developed a disposable aerosol-conducting airway connector for infants that is intended to simplify the delivery of aerosolized medications (including our aerosolized KL4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support. This device introduces aerosolized medications directly at the patient interface and minimizes the number of connections in the ventilator circuit. We have registered this device in the U.S. as a Class I, exempt medical device under the name AFECTAIR® and it is currently commercially available in the U.S.

#### **Business and Pipeline Programs Update**

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

Following are updates to our pipeline programs since the filing of our 2013 Form 10-K:

· With the commercial introduction of SURFAXIN underway, our commercial and medical teams are focused on forming relationships with key constituents in our target hospitals, including neonatologists, pharmacists, respiratory therapists, NICU nurses and other staff in the NICU with the goal of obtaining formulary acceptance and, ultimately, product utilization in our target hospitals. We also are focused on conducting in-service training to assure that SURFAXIN is administered in a safe and consistent manner.

Although not an indicator or predictor of revenue, formulary acceptance for SURFAXIN is a necessary prerequisite to be able to sell SURFAXIN drug product to a hospital and realize revenues. In the brief period that SURFAXIN has been available, our early experience suggests that the time required to have SURFAXIN reviewed by hospital committees, accepted on hospital formulary, purchased by the hospital pharmacy, and ultimately used in the NICU is considerably longer than expected. As a result, while we continue to believe that we will be able to meet our long term objectives for SURFAXIN, we anticipate that our short term revenues will be modest in the next several years.

SURFAXIN is the first synthetic, peptide-containing alternative to the previously available animal-derived surfactants. Our experience to date indicates that, to properly explain the method of administration and the potential benefits of SURFAXIN, including both potential medical and pharmacoeconomic benefits, it is important to emphasize medical education and scientific discussions with formulary committees to better inform their process. Accordingly, in the second quarter of 2014, we are resizing and realigning our commercial and medical affairs teams to emphasize medical education balanced with an appropriate sales effort, and to focus on securing formulary acceptance with hospitals that we believe are centers of excellence whose reputation and influence is strong both regionally and nationally. We expect that this realignment could result in a reduction in expense in the second half of 2014 of approximately \$1.0 million per quarter compared to our recent historical expense. As we monitor our progress, our strategy is to routinely assess and adjust our tactical plan and make appropriate additional investments if needed to assure that we maximize potential formulary uptake and SURFAXIN sales revenue.

- · Our AEROSURF phase 2 clinical program is underway. The initial phase 2a clinical trial is designed to assess the safety and tolerability of aerosolized KL4 surfactant in premature infants 29 to 32 weeks gestational age receiving nCPAP for RDS. Results are expected in the third quarter of 2014. We currently are planning for, and expect to initiate, a phase 2b clinical study in the second half of 2014 and expect to complete it in the second half of 2015.
- We are progressing with our long-term manufacturing strategy. We are continuing to explore possible alternatives that could enable longer-term utilization of our Totowa Facility, the lease for which currently is scheduled to expire on June 30, 2015. We are also pursuing potentially manufacturing KL4 surfactant using third-party CMOs. Since 2012, we having been working with DSM to complete a technology transfer of our liquid KL4 surfactant manufacturing process to DSM and we have entered into a supply agreement with DSM that provides for the manufacture of commercial supply of SURFAXIN drug product through December 31, 2015, with such potential extensions as we may agree. We also are working to identify a second CMO to manufacture SURFAXIN drug product. Although we believe that we will successfully execute our plan to provide for the long-term availability of SURFAXIN drug product, there can be no assurance that we will be successful. See our 2013 Form 10-K "Item 1A Risk Factors 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 recently announced that we have secured three additional patents in the U.S., including two patents containing composition of matter and method of making claims for our lyophilized KL4 surfactant, which extend to 2033, and one related to our novel AFECTAIR aerosol-conducting airway connector that extends to April 2029. These patents are indicative of our efforts to protect the long-term commercial potential of our KL4 surfactant and aerosol delivery technologies. our lyophilized KL4 surfactant is being developed initially for our AEROSURF development program. Our longer term goal is to develop our technologies to address other potential indications that could benefit from our proprietary KL4 surfactant.

#### CRITICAL ACCOUNTING POLICIES

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

#### RESULTS OF OPERATIONS

#### **Net Loss and Operating Loss**

The net loss for the three months ended March 31, 2014 and 2013 was \$11.5 million (or \$0.14 net loss per share) and \$12.6 million (or \$0.29 net loss per share), respectively. The decrease in net loss from 2013 to 2014 was due to the decrease in operating loss, partially offset by a \$0.9 million increase in interest expense associated with the Deerfield Loan.

The operating loss for the three months ended March 31, 2014 and 2013 was \$10.8 million and \$12.6 million, respectively. The decrease in operating loss from 2013 to 2014 was due to (i) a \$1.2 million decrease in costs to develop and manufacture clinic-ready CAG devices for use in the AEROSURF phase 2a clinical study, and (ii) a \$1.2 million decrease in purchases of drug product of active pharmaceutical ingredients (APIs) used in the manufacture of SURFAXIN our aerosolized KL4 surfactant for AEROSURF development program.

#### **Product Sales**

In accordance with our revenue recognition policy, we recognize revenue once product has been sold through to the hospital and all revenue recognition criteria have been met. For the three months ended March 31, 2014, we recognized revenue in the amount of \$28,000.

#### Cost of product sales

Cost of product sales for the three months ended March 31, 2014 includes an increase of \$766,000 in inventory reserves for SURFAXIN finished goods inventories that are not anticipated to be recoverable through the commercial sale of the product during the initial launch period due to product expiration.

#### **Research and Development Expenses**

Our research and development expenses are charged to operations as incurred and are tracked by category rather than by development project. As many of our research and development activities form a foundation for the development of our KL<sub>4</sub> surfactant and drug delivery technologies, they are expected to benefit more than a single project. For that reason, we cannot reasonably estimate the costs of our research and development activities on a project-by-project basis. We believe that tracking our expenses by category is a more accurate method of accounting for these activities. Our research and development costs consist of expenses associated with (a) product development and manufacturing, (b) medical and regulatory operations, (c) direct preclinical and clinical programs, and (d) other related expenses.

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

(in thousands)	Three Months Ended March 31,			
Research and Development Expenses		2014		2013
Product development and manufacturing	\$	3,623	\$	6,824
Medical and regulatory operations		1,633		1,451
Direct preclinical and clinical programs		333		197
Total Research & Development Expenses	\$	5,590	\$	8,472

Research and development expenses for the three months ended March 31, 2014 and 2013 include non-cash charges associated with stock-based compensation and depreciation of \$0.4 million and \$0.3 million, respectively.

#### Product Development and Manufacturing

Product development and manufacturing includes (i) the cost of our manufacturing operations, both in-house and with our CMOs, validation activities and quality assurance and analytical chemistry capabilities to support production of drug supply for our KL4 surfactant products in conformance with current good manufacturing practices (cGMP), and of medical devices, including AFECTAIR, WARMING CRADLE® and CAG, in accordance with Quality System Regulations (QSR), (ii) design and development activities related to our CAG device for use in our AEROSURF phase 2 clinical program; and (iii) 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 March 31, 2014 decreased \$3.2 million compared to the same period in 2013, due to (i) investments of \$1.2 million in 2013 to complete development activities for our clinic-ready CAG device for use in our AEROSURF phase 2 clinical trials, including work that began in June 2012 with Battelle Memorial Institute (Battelle), which assisted with the design and testing, and manufactured a supply of clinic-ready CAG devices for use in the initial AEROSURF phase 2a clinical trial; (ii) a reduction of \$1.2 million in purchases of APIs used in the manufacture of SURFAXIN commercial drug product, and our lyophilized KL4 surfactant for use in preclinical and clinical development activities, including to complete the technology transfer of, and further develop our KL4 surfactant manufacturing process at DSM Pharmaceuticals, Inc. (DSM), and activities to develop a clinic-ready CAG and prepare for our AEROSURF phase 2 clinical program; and (iii) \$0.9 million of costs capitalized to SURFAXIN inventory in 2014.

#### Medical and Regulatory Operations

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

Medical and regulatory operations costs for the three months ended March 31, 2014 increased \$0.2 million compared to the same period in 2013, due to an increased investment in our medical organization to execute our AEROSURF phase 2 clinical program.

#### **Direct Preclinical and Clinical Programs**

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

Direct preclinical and clinical programs expenses for the three months ended March 31, 2014 increased \$0.1 million compared to the same period in 2013. Costs for the three months ended March 31, 2014 consisted of AEROSURF Phase 2a clinical trial and related activities. Costs for the three months ended March 31, 2013 consisted of pre-clinical activities to support our AEROSURF development program and related activities.

We anticipate that direct clinical program costs associated with conducting the AEROSURF phase 2 clinical program will be approximately \$10 - 11 million for 2014 and through the anticipated completion of the AEROSURF phase 2 program in 2015.

#### Research and Development Projects - Updates

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete individual projects in development are not reasonably estimable. With every phase of a development project, there are unknowns that may significantly affect cost projections and timelines. In view of the number and nature of these factors, many of which are outside our control, the success, timing of completion and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. Certain of the risks and uncertainties affecting our ability to estimate projections and timelines are discussed in the Risk Factors Section and elsewhere in this Quarterly Report on Form 10-Q and in our 2013 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 research and development projects have been focused initially on the management of RDS in premature infants, and include (i) SURFAXIN liquid instillate, which was approved by the FDA in 2012, (ii) our lyophilized KL4 surfactant, which we are developing initially for use in our AEROSURF development program and, if we are able to undertake a development plan that would be both capital efficient and capable of implementation within a reasonable time, potentially, in a SURFAXIN LS development program; and (iii) our aerosol delivery technology, in particular the development of a clinic-ready CAG device to support our AEROSURF phase 2 clinical program. These and our other development programs are described in our 2013 Form 10-K, "Item 1 – Business – Proprietary Platform – Surfactant and Aerosol Technologies," and "- Surfactant Replacement Therapy for Respiratory Medicine," and in our other periodic filings with the SEC.

To prepare for initiation of the AEROSURF phase 2 clinical program, during 2012 through 2013, we invested approximately \$7 million to develop a clinic-ready CAG device and our lyophilized KL4 surfactant manufacturing process at DSM. As noted above, we anticipate that direct clinical program costs associated with conducting the AEROSURF phase 2 clinical program will be approximately \$10 - 11 million for 2014 and through the completion of phase 2b in 2015. We also plan to continue securing appropriate capabilities to support the further advancement of AEROSURF, including for manufacturing development of our lyophilized KL4 surfactant, the conduct of a phase 3 clinical program, and the further development of a CAG device suitable for use in a phase 3 clinical program and, if successful, commercial use.

At the present time, we are focusing our efforts primarily on the commercial introduction of SURFAXIN and development of AEROSURF through the phase 2 clinical trials. We also believe that, we may be able to leverage the information, data and know-how that we gain from our work with SURFAXIN and AEROSURF to support development of a robust product pipeline that could address serious critical care respiratory conditions in larger children and adults in pediatric intensive care units (PICUs) and adult intensive care units (ICUs), including potentially acute lung injury (ALI), chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF).

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

#### **Selling, General and Administrative Expenses**

(in thousands)	March 31,			
		2014		2013
Selling, General and Administrative Expenses	\$	4,423	\$	4,220

Selling, general and administrative expenses consist of the costs of sales and marketing activities, executive management, business development, intellectual property, finance and accounting, legal, human resources, information technology, facilities and other administrative costs.

Selling, general and administrative expenses for the three months ended March 31, 2014 increased \$0.2 million compared to the same period in 2013 due to an increased investment in our marketing and field-based sales force to execute the commercial introduction of SURFAXIN and the AFECTAIR device for infants.

#### **Change in Fair Value of Common Stock Warrant Liability**

(in thousands)	Three Months Ended March 31,		led	
	201	4	20	013
Change in fair value of common stock warrant liability	\$	378	\$	162

We account for common stock warrants in accordance with applicable accounting guidance provided in ASC Topic 815 "Derivatives and Hedging – Contracts in Entity's Own Equity" (ASC 815), either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. Derivative warrant liabilities are valued at the date of initial issuance and as of each subsequent balance sheet date using the Black-Scholes or trinomial pricing models, depending on the terms of the applicable warrant agreement. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in the fair value of common stock warrant liability." See, Note 6 to our Consolidated Financial Statements in this Quarterly Report on Form 10-Q, and our 2013 Form 10-K, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – Change in Fair Value of Common Stock Warrant Liability."

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

#### Other Income and (Expense)

(in thousands)	Three months ended March 31,				
		2014		2013	
Interest income	\$	2	\$	1	
Interest expense		(1,093)		(178)	
Other income / (expense), net	\$	(1,091)	\$	(177)	

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

Interest expense in 2013 consists of interest expense associated with the Deerfield Loan (*see*, Note 7 to our Consolidated Financial Statements in this Quarterly Report on Form 10-Q) and interest expense incurred under our equipment financing facilities.

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

(in thousands)	Three months ended March 31,			
		2014		2013
Cash interest expense	\$	647	\$	113
Non-cash amortization of debt discount		439		57
Amortization of debt costs		5		5
Total interest expense	\$	1,091	\$	175

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

#### LIQUIDITY AND CAPITAL RESOURCES

#### Overview

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

As of March 31, 2014, we had cash and cash equivalents of \$75.9 million and long-term debt of \$30 million (\$18.8 million net of discount) under our Deerfield Loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (*see*, Note 7, " – Deerfield Loan," to our Consolidated Financial Statements in this Quarterly Report on Form 10-Q). Before any additional financings, including under our ATM Program (*see*, "– Common Stock Offerings – At-the-Market Program (ATM Program)," and Note 11, "Stockholders' Equity – ATM Program," to the consolidated financial statements in our 2013 Form 10-K), we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the third quarter of 2015.

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

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

As of March 31, 2014, we had outstanding warrants to purchase approximately 14.5 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, warrants to purchase 7 million shares were issued to Deerfield in connection with the Deerfield Loan at an exercise price of \$2.81 per share. The Deerfield Warrants may be exercised for cash or on a cashless basis. In lieu of paying cash upon exercise, the holders also may elect to reduce the principal amount of the Deerfield Loan in an amount sufficient to satisfy the exercise price of the Deerfield Warrants. In addition to the Deerfield Warrants, we have outstanding five-year warrants issued in February 2011 to purchase approximately 4.6 million shares of common stock that contain anti-dilution provisions that adjust the exercise price if we issue any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the warrants. These warrants currently have an exercise price of \$1.50 per share. 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 would make exercise of outstanding warrants likely, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. Moreover, if our outstanding warrants are exercised, such exercises likely will be at a discount to the then-market value of our common stock and have a dilutive effect on the value of our shares of common stock at the time of exercise.

As of March 31, 2014, 150 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, and approximately 42.1 million shares of common stock were available for issuance and not otherwise reserved.

Although we currently believe that we will be able to successfully execute our business strategy, there can be no assurance that our AEROSURF development program will be successful within our anticipated time frame, if at all, that we will succeed in obtaining the necessary regulatory approvals in the U.S. and other markets, that any approved product, including SURFAXIN, will be commercially viable, that the ATM Program will be available when needed, if at all, or that we will be able to obtain additional capital when needed on acceptable terms, if at all, that we will be successful. We will require significant additional capital to satisfy debt obligations and sustain operations, and to complete the development and, if they are approved, support the commercial introduction of our products. Failure to secure the necessary additional capital would have a material adverse effect on our business, financial condition and results of operations. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

#### Cash Flows

As of March 31, 2014, we had cash and cash equivalents of \$75.9 million compared to \$86.3 million as of December 31, 2013. Cash outflows before financing activities for the three months ended March 31, 2014 consisted of \$10.3 million used for ongoing operating activities and \$0.5 million for purchases of property and equipment. Cash provided by financing activities were \$0.4 million of proceeds from the exercise of warrants and stock options.

#### **Operating Activities**

Net cash used in operating activities for the three months ended March 31, 2014 and 2013 was \$10.3 million and \$10.2 million, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital.

#### **Investing Activities**

Net cash used in investing activities for the three months ended March 31, 2014 and 2013 represents capital expenditures of \$0.5 million and \$0.1 million, respectively. The increase in capital expenditures is due to timing of routine equipment purchases.

#### Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2014 and 2013 was \$0.4 million and \$9.9 million, respectively. Net cash provided by financing activities for the three months ended March 31, 2014 represents proceeds from the exercise of warrants and stock options. Net cash provided by financing activities for the three months ended March 31, 2013 represents the first advance of \$10.0 million (\$9.9 million, net) under the Deerfield Loan upon execution of the agreement in February 2013.

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. As of March 31, 2014, after reserves for unexercised warrants and amounts remaining under our ATM Program, approximately \$11.0 million remained available under the 2011 Universal Shelf. The 2011 Universal Shelf will expire in June 2014.

#### At-the-Market Program (ATM Program)

We have an At-the-Market Equity Offering Sales Agreement with Stifel, under which Stifel, as our exclusive agent, at our discretion and at such times that we may determine from time to time, may sell up to a maximum of \$25 million of our common stock over a three-year period. We are not required to sell any shares at any time during the term of the ATM Program. We have agreed to pay Stifel a commission of 3% of gross proceeds of any sales of shares. *See*, Note 11, "Stockholders' Equity – ATM Program," to the consolidated financial statements in our 2013 Form 10-K. As of March 31, 2014, approximately \$23 million shares of common stock remained available under the ATM Program.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

#### ITEM 4. CONTROLS AND PROCEDURES

#### Evaluation of disclosure controls and procedures

Our management, including our President and Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal financial officer), does not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our President and Chief Executive Officer and our Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer and our Chief Financial Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

#### Changes in internal controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended March 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

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

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

#### ITEM 1A. RISK FACTORS

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

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

During the three months ended March 31, 2014, we issued 8,750 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during 2014. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(2) of the Act.

#### ITEM 6. EXHIBITS

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

#### **SIGNATURES**

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

Discovery Laboratories, Inc. (Registrant)

Date: May 12, 2014 By: /s/ John G. Cooper

John G. Cooper

President and Chief Executive Officer

Date: May 12, 2014 By: /s/ John Tattory

John Tattory

Chief Financial Officer

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# INDEX TO EXHIBITS

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

Amended and Restated Certificate of Incorporation 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  3.2 Certificate of Designations, Preferences and Rights of Series A Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004  3.3 Amended and Restated By-Laws of Discovery, as amended effective September 3, 2009  4.1 Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company  4.2 Warrant Agreement dated December 12, 2008 by and between Kingsbridge Capital Limited and Discovery  4.3 Form of Warrant to Purchase Common Stock issued in May 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.  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.  Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 15, 2008.  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.
Junior Participating Cumulative Preferred Stock of Discovery, dated February 6, 2004  3.3 Amended and Restated By-Laws of Discovery, as amended effective September 3, 2009  4.1 Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company  4.2 Warrant Agreement dated December 12, 2008 by and between Kingsbridge Capital Limited and Discovery  4.3 Form of Warrant to Purchase Common Stock issued in May 2009  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.  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.
September 3, 2009  Report on Form 8-K, as filed with the SEC on September 4, 2009.  1.1 Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company  1.2 Warrant Agreement dated December 12, 2008 by and between Kingsbridge Capital Limited and Discovery  1.3 Form of Warrant to Purchase Common Stock issued in May 2009  Report on Form 8-K, as filed with the SEC on September 4, 2009.  1.4 Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 15, 2008.
between Discovery and Continental Stock Transfer & Trust Company  4.2 Warrant Agreement dated December 12, 2008 by and between Kingsbridge Capital Limited and Discovery  4.3 Form of Warrant to Purchase Common Stock issued in May 2009  Report on Form 8-K, as filed with the SEC on February 6, 2004.  Report on Form 8-K, as filed with the SEC on December 15, 2008.  Incorporated by reference to Exhibit 10.3 to Discovery's Current
Kingsbridge Capital Limited and Discovery  Report on Form 8-K, as filed with the SEC on December 15, 2008.  4.3 Form of Warrant to Purchase Common Stock issued in May 2009  Incorporated by reference to Exhibit 10.3 to Discovery's Current
Form of Warrant to Purchase Common Stock issued in February 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.
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.
Warrant Agreement dated June 11, 2010 by and between Kingsbridge 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.
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.

Exhibit No.	Description	Method of Filing
4.8	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.
4.9	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.
4.10+	Form of Warrant dated February 13, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) under a Facility Agreement dated as of February 13, 2012 between Discovery and Deerfield	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2013.
4.11+	Form of Warrant dated December 3, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) on December 3, 2013 under a Facility Agreement dated as of February 13, 2012 between Discovery and Deerfield	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on December 6, 2013.
<u>10.1*</u>	Employment Agreement dated as of March 21, 2014 between Discovery and John Tattory	Filed herewith.
<u>31.1</u>	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
<u>31.2</u>	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act	Filed herewith.
<u>32.1</u>	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith.
101.1	The following consolidated financial statements from the Discovery Laboratories, Inc. Annual Report on Form 10-Q for the quarter ended March 31, 2014, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of March 31, 2014 (unaudited) and December 31, 2013, (ii) Statements of Operations (unaudited) for the three months ended March 31, 2014 and March 31, 2013, (iii) Statements of Cash Flows (unaudited) for the three months ended March 31, 2014 and March 31, 2013, and (v) Notes to consolidated financial statements.	

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

<sup>+</sup> Confidential treatment requested as to certain portions of these exhibits. Such portions have been redacted and filed separately with the Commission.

<sup>\*</sup> 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.

#### EMPLOYMENT AGREEMENT

This Employment Agreement (the "<u>Agreement</u>") is made as of March 21, 2014, by and between Discovery Laboratories, Inc., a Delaware corporation (the "<u>Company</u>"), and John A. Tattory ("<u>Executive</u>"), subject to the terms and conditions defined in this Agreement.

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

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

- 1. <u>Certain Definitions.</u> Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.
- 2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through March 31, 2015; provided, however, that commencing on April 1, 2015 and on each April 1 thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such renewal date, either party shall have given notice that such party does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions hereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the expiration date of the then-current Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination. On the Date of Termination, Executive hereby resigns all employment and related job duties and responsibilities with the Company, including, without limitation any and all positions on any committees or boards of the Company or any affiliated company. Executive agrees to sign all documentation evidencing the foregoing as may be presented to Executive for signature by the Company.
  - 3. Executive's Duties and Obligations.
- (a) <u>Duties.</u> Executive shall serve as the Company's Senior Vice President and Chief Financial Officer. Executive shall be responsible for all duties customarily associated with a Senior Vice President and Chief Financial Officer in a publicly-traded company.
- (b) <u>Location of Employment.</u> Executive's principal place of business shall be at the Company's headquarters to be located within thirty (30) miles of Warrington, Pennsylvania. In addition, Executive acknowledges and agrees that the performance by Executive of Executive's duties shall require frequent travel including, without limitation, overseas travel from time to time.
- (c) <u>Proprietary Information and Inventions Matters.</u> In consideration of the covenants contained herein, Executive has executed and agrees to be bound by the Company's standard form of Proprietary Information and Inventions, Non-Solicitation and Non-Competition Agreement (the "<u>Confidentiality Agreement</u>"), a form of which is attached to this Agreement as Exhibit B. Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

#### 4. <u>Devotion of Time to Company's Business.</u>

- (a) <u>Full-Time Efforts.</u> During Executive's employment with the Company, Executive shall devote substantially all of Executive's time, attention and efforts to the proper performance of Executive's implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.
- (b) <u>No Other Employment.</u> During Executive's employment with the Company, Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board of Directors of the Company (the "Board").
- (c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity compete with the Company in the business of developing or commercializing (i) pulmonary surfactants or any other category of compounds which form the basis of the Company's material drug products, or (ii) any material medical device products under development by the Company, including without limitation the Company's capillary aerosol generator, series of aerosol-conducting airway connectors and related componentry, and similar medical devices; in each case, as determined in good faith by the Board on the Date of Termination. During the Term and for 18 months from the Date of Termination, Executive shall not solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the six (6) months preceding the Date of Termination; provided, that nothing herein shall prevent Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of Executive or (ii) if such discussions shall be held as a result of, or any employment shall be the result of, the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specific
- (d) <u>Injunctive Relief.</u> In the event that Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

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

## 5. <u>Compensation and Benefits.</u>

- (a) <u>Base Compensation.</u> During the Term, the Company shall pay to Executive (i) base annual compensation ("<u>Base Salary</u>"), effective as of March 24, 2014, of \$260,000, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; <u>provided</u>, <u>however</u>, that any increase in Base Salary shall be solely within the discretion of the Company. Executive's Base Salary shall not be subject to reduction from the level in effect hereunder from time to time, other than pursuant to a salary reduction program of general application to contract executives of the Company.
- (b) Bonuses. During the Term, Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, based upon a target Annual Bonus Amount of 30% of Base Salary, as may be awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of a similar level in connection with comparable equity bonuses awarded by the Company.
- (c) Benefits. During the Term, Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives of a similar level or to other employees (including, without limitation, profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. If a conflict should exist between similar benefits afforded under any Company policy and the benefits afforded under this Agreement, the Company policy shall control, except to the extent that this Agreement shall provide for greater benefits, in which event the terms of this Agreement shall control. Anything contained herein to the contrary notwithstanding, throughout the Term, Executive shall be entitled to receive life insurance on behalf of Executive's named beneficiaries in an amount equal to the lesser of (i) Executive's then current annual salary for the Term of this Agreement and (ii) if less, the maximum amount available under the Company's insurance program, at no cost to Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such insurance.

- (d) <u>Vacations.</u> During the Term, Executive shall be entitled to 25 days paid vacation per year, or such greater amount as may be earned under the Company's standard vacation policy, to be earned ratably throughout the year. Vacation days may be carried from one year to the next in accordance with the Company vacation policy.
- (e) <u>Reimbursement of Business Expenses.</u> Executive is authorized to incur reasonable expenses in carrying out Executive's duties and responsibilities under this Agreement and the Company shall reimburse Executive for all such expenses, in accordance with reasonable policies of the Company.

# 6. <u>Change of Control Benefits.</u>

- (a) <u>Bonus.</u> Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period that is at least equal to the Annual Bonus Amount; <u>provided</u>, that Executive is employed on the last day of such fiscal year. Such bonuses will be paid no later than the 15<sup>th</sup> day of the third month following the end of such fiscal year.
- (b) Options. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested and, with respect to restricted stock, all restrictions shall be lifted upon the Change of Control Date. In the case of any Change of Control in which holders of the Company's common stock receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) Executive shall be permitted to exercise Executive's options at a time and in a fashion that will entitle Executive to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

# 7. <u>Termination of Employment.</u>

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

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

- (b) <u>Termination by the Company without Cause or by Executive for Good Reason.</u> If (x) Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) Executive terminates employment with Good Reason, then Executive will receive the amounts set forth in Section 7(a)(i) and, on the condition that the Executive signs a separation agreement containing a plenary release of claims in a form acceptable to the Company within fifty (50) days after the Date of Termination (or such shorter period specified in such plenary release) and such plenary release becomes final, binding and irrevocable, the Executive shall also be entitled to receive the following from the Company:
- (i) A pro rata bonus equal to the Executive's Annual Bonus Amount (A) multiplied by the fraction obtained by dividing the aggregate amount of actual bonuses paid to the Company's other employment contract executives for the year that includes the Date of Termination by such employment contract executives' aggregate target bonuses for the year that includes the Date of Termination, multiplied by (B) the fraction obtained by dividing the number of days in the year through the Date of Termination by 365, which amount shall be paid when the Company's other employment contract executives are paid;
- (ii) An amount equal to 1 times the sum of (A) Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Annual Bonus Amount, payable in equal installments in accordance with the Company's regular payroll schedule, from the Date of Termination to the date that is 12 months after the Date of Termination (the "Severance Period") provided, however, that each installment payable before the plenary release becomes final, binding and irrevocable shall not be paid to the Executive until such plenary release becomes final, binding and irrevocable;
- (iii) During the Severance Period, if Executive elects to continue Company medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Company shall continue to pay the Company's costs of such benefits as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company. If for any reason COBRA coverage is unavailable at any time during the Severance Period, the Company shall reimburse Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for Executive to purchase medical and dental coverage for Executive and Executive's dependents that is substantially equivalent to the medical and dental coverage that Executive and Executive's dependents were receiving immediately prior to the Date of Termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under the Company's plans. Company's obligation under this Section 7(b)(iii) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

- (iv) Upon the date that the plenary release becomes final, binding and irrevocable, notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and the Executive, all vested stock options to acquire Company stock and all other similar equity awards held by the Executive as of the Date of Termination shall continue to be exercisable during the Severance Period; and
  - (v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company.

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

- (c) <u>Termination in connection with a Change of Control.</u> If Executive's employment is terminated by the Company other than for Cause or by Executive for Good Reason during the Effective Period, then Executive shall be entitled to receive the following from the Company:
  - (i) All amounts and benefits described in Section 7(a)(i) above;
- (ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Annual Bonus Amount multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;
- (iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to 1.5 times the sum of (A) Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Annual Bonus Amount; provided, however, that if Executive's employment is terminated prior to the consummation of a Change of Control but under circumstances that would cause the Change of Control Date to precede the date that the Change of Control is consummated, such amount will be paid in equal installments in accordance with the Company's regular payroll schedule over the Severance Period described in Section 7(b)(ii);
- (iv) If Executive elects to continue Company medical benefits under COBRA, for a period of 18 months following the Date of Termination (the "Benefit Period"), the Company shall continue to pay the Company's costs of such benefits as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company. If for any reason COBRA coverage is unavailable at any time during the Benefit Period, the Company shall reimburse Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for Executive to purchase medical and dental coverage for Executive and Executive's dependents that is substantially equivalent to the medical and dental coverage that Executive and Executive's dependents were receiving immediately prior to the Date of Termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under the Company's plans. Company's obligation under this Section 7(b)(iii) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

- (v) Notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms; and
  - (vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company.

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

## 8. <u>Notice of Termination.</u>

- (a) Any termination of Executive's employment by the Company for Cause, or by Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination (at least 30 days in the case of Notice of Termination given by Executive for Good Reason), (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.
- (b) A Termination of Employment of Executive will not be deemed to be for Good Reason unless Executive gives the Notice of Termination provided for herein within 12 months after Executive has actual knowledge of the act or omission of the Company constituting such Good Reason and Executive gives the Company a 30 day cure period to rectify or correct the condition or event that constitutes Good Reason.
- 9. <u>Mitigation of Damages.</u> Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by Executive as the result of self-employment or employment by another employer or otherwise.

## 10. Excess Parachute Excise Tax.

- Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or (a) distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), the Company will automatically reduce such Payments to the extent, but only to the extent, necessary so that no portion of the remaining Payments will be subject to the Excise Tax, unless the amount of such Payments that the Executive would retain after payment of the Excise Tax and all applicable Federal, state and local income taxes without such reduction would exceed the amount of such Payments that the Executive would retain after payment of all applicable Federal, state and local taxes after applying such reduction. Unless otherwise elected by the Executive, to the extent permitted under Code Section 409A, such reduction shall first be applied to any stock options, restricted stock or any other form of equity compensation (Equity Compensation") that is subject to exercise at a price per share that exceeds the closing price of the Company's common stock on the trading day immediately preceding the Change of Control, and thereafter pro rata among (i) severance payments payable to the Executive under this Agreement in reverse order of receipt, (ii) any remaining compensation in respect of Equity Compensation provided under this Agreement, starting with those options with the smallest spread between fair market value and exercise price first, and any restricted stock or restricted stock units, and (iii) any compensation related to continuation of benefits in reverse order of receipt.
- (b) All determinations required to be made under this Section 10, including the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and Executive within 15 business days of the receipt of notice from Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. If the Accounting Firm determines that no Excise Tax is payable by Executive, it shall furnish Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and Executive.
- 11. <u>Legal Fees.</u> All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.
- 12. <u>Notices.</u> All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

if to the Board or the Company:	
Discovery Laboratories, Inc. 2600 Kelly Road, Suite 100 Warrington, PA 18976 Attn: General Counsel	
if to Executive:	
The address on file with the records of the Company	

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

- 13. <u>Withholding.</u> The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.
- 14. <u>Entire Agreement.</u> This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

## 15. <u>Arbitration.</u>

- (a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this Agreement or any dispute or claim between Executive and the Company or its officers, directors, agents, or employees (a "<u>Dispute</u>"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand." Such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.
- (b) The Dispute shall be resolved by a single arbitrator in an arbitration administered by the American Arbitration Association in accordance with its Employment Arbitration Rules and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The decision of the arbitrator shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrator may be ordered by any court of competent jurisdiction.
- (c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).
- (d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Employment Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

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

- (ii) The decision of the arbitrator, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrator hereunder.
- (iii) The arbitrator shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory and punitive damages if authorized by applicable law.
- (iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.
- (v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney's fees and defense costs.

## 16. <u>Miscellaneous.</u>

- (a) <u>Governing Law.</u> This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.
- (b) <u>Amendments.</u> No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.
- (c) <u>Severability.</u> If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

- (d) <u>Binding Effect.</u> This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.
- (e) <u>Successors and Assigns.</u> Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.
- (f) <u>Remedies Cumulative; No Waiver.</u> No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.
- (g) <u>Survivorship.</u> Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.
- (h) <u>Entire Agreement.</u> This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.
- (i) <u>Counterparts.</u> This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.
- 17. <u>No Contract of Employment.</u> Nothing contained in this Agreement will be construed as a right of Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge Executive with or without Cause.
- 18. Section 409A of the Code. The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from, Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be construed and interpreted in accordance with such intent. Executive's termination of employment (or words to similar effect) shall not be deemed to have occurred for purposes of this Agreement unless such termination of employment constitutes a "separation from service" within the meaning of Code Section 409A and the regulations and other guidance promulgated thereunder.

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

- To the extent any reimbursement of costs and expenses provided for under this Agreement constitutes taxable income to Executive for Federal income tax purposes, such reimbursements shall be made no later than December 31 of the calendar year next following the calendar year in which the expenses to be reimbursed are incurred. With regard to any provision herein that provides for reimbursement of expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year. Any tax gross-ups provided for under this Agreement shall in no event be paid to Executive later than the December 31 of the calendar year following the calendar year in which the taxes subject to gross-up are incurred or paid by Executive.
- If any amount under this Agreement is to be paid in two or more installments, for purposes of Code Section 409A each installment (c) shall be treated as a separate payment.
- Executive Acknowledgement. Executive hereby acknowledges that Executive has read and understands the provisions of this Agreement, that Executive has been given the opportunity for Executive's legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that Executive has received a copy of this Agreement.

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

Discovery Laboratories, Inc.

Dated: April 9, 2014

By: /s/ Kathryn A. Cole

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Name: Kathryn A. Cole /s/ John A. Tattory John A. Tattory

Senior Vice President, Human Resources

#### **EXHIBIT A**

- (a) "Annual Bonus Amount" means the current year's target annual bonus amount for the Executive.
- (b) **"Beneficiary"** means any individual, trust or other entity named by Executive to receive the payments and benefits payable hereunder in the event of the death of Executive. Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by Executive, or if no designated Beneficiary survives Executive, then the payment and benefits provided under this Agreement, if any, will be paid to Executive's estate, which shall be deemed to be Executive's Beneficiary.
- (c) "Cause" means: (i) Executive's willful and continued neglect of Executive's duties with the Company (other than as a result of Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to Executive by the Company which specifically identifies the manner in which the Company believes that Executive has neglected his duties; (ii) the final conviction of Executive of, or an entering of a guilty plea or a plea of no contest by Executive to, a felony; or (iii) Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

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

(d) "Change of Control" means the occurrence of any one of the following events:

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

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

- (iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "<u>Business Combination</u>") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, 50% or more of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or
- (iv) any "person" (as defined in Sections 13(d) and 14(d) of the Exchange Act) acquires all or substantially all of the assets of the Company within any 12 consecutive month period.

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

- (e) "Change of Control Date" means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.
  - (f) "Code" means the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.
- (g) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

- (h) **"Disability"** means a mental or physical condition that renders Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give Executive at least 30 days' written notice that it considers the time period for disability to be running.
- (i) **"Effective Period"** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.
- (j) "Good Reason" means, unless Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to Executive of any duties materially inconsistent with Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a material reduction in Executive's Base Salary by the Company; (iii) the relocation of Executive's office to a location more than 30 miles from Warrington, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); or (v) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

#### **EXHIBIT B**

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

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

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

- 5. <u>Ownership, Disclosure and Assignment of Proprietary Information and Inventions.</u> In addition, I hereby agree as follows:
- (a) Ownership and Assignment. All Proprietary Information is, and shall be, the sole and exclusive property of the Company and its assigns, and the Company and its assigns shall be the sole and exclusive owner of all Proprietary Information, including, but not limited to, trade secrets, inventions, patents, trademarks, copyrights, and all other rights in connection with such Proprietary Information. I agree that I have no rights in such Proprietary Information. I hereby assign, and shall assign, to the Company and its assigns any and all rights, title and interest I may have or acquire in such Proprietary Information. Any copyrightable work prepared in whole or in part by me in the course of my employment shall be deemed "a work made for hire" under applicable copyright laws, and the Company and its assigns shall own all of the rights in any copyright.
- (b) Return of Materials and Property. All documents, records, apparatus, equipment, data bases, data and information stored in computers or on electronic disks, and other electronic, computer, intellectual, and physical property ("Materials and Property"), whether or not pertaining to Proprietary Information, furnished to me by the Company or produced by me or others in connection with employment, shall be and remain the sole and exclusive property of the Company. I shall return to the Company all such Materials and Property as and when requested by the Company. Even if the Company does not so request, I shall return all such Materials and Property upon termination of employment by me or by the Company for any reason, and I will not take with me any such Materials or Property, or any reproduction thereof, upon such termination.
- (c) <u>Notification</u>. During the term of my employment and for one (1) year thereafter, I will promptly disclose to the Company, or any persons designated by it, all improvements, inventions, intellectual property, works of authorship, formulas, ideas, processes, techniques, discoveries, developments, designs, innovations, know-how and data, and creative works in which copyright and/or unregistered design rights will subsist in various media (all collectively called herein, "Inventions"), whether or not such Inventions are patentable, which I make or conceive, contribute to, reduce to practice, or learn, either alone or jointly with others.
- (d) Ownership of Inventions. I agree and acknowledge that all Inventions which I make, conceive, develop, or reduce to practice (in whole or in part, either alone or jointly with others) at any time during my employment by the Company, and (i) which were created using the equipment, supplies, facilities or trade secret information of the Company, or (ii) which were developed during the hours for which I was compensated by the Company, or (iii) which relate, at the time of conception, creation, development or reduction to practice, to the business of the Company or to its actual or demonstrably anticipated research and development, or (iv) which result from any work performed by me for the Company, shall be the sole and exclusive property of the Company and its assigns (and to the fullest extent permitted by law shall be deemed works made for hire), and the Company and its assigns shall be the sole and exclusive owner of all Inventions, patents, copyrights and all other rights in connection therewith. I hereby assign to the Company any and all rights I may have or acquire in such Inventions. I agree that any Invention required to be disclosed under paragraph (c), above, within one (1) year after the termination of my employment shall be presumed to have been conceived or made during my employment with the Company and will be assigned to the Company unless and until I prove and establish to the contrary.

- (e) Assistance and Cooperation. With respect to Inventions described in paragraph (d), above, I will assist the Company in every proper way (but at the Company's expense) to obtain, and from time to time enforce, patents, copyrights or other rights on these Inventions in any and all countries, and will execute all documents reasonably necessary or appropriate for this purpose. This obligation shall survive the termination of my employment. In the event that the Company is unable for any reason whatsoever to secure my signature to any document reasonably necessary or appropriate for any of the foregoing purposes (including renewals, extensions, continuations, divisions or continuations in part), I hereby irrevocably designate and appoint the Company, and its duly authorized officers and agents, as my agents and attorneys-in-fact to act for and in my behalf and instead of me, but only for the purpose of executing and filing any such document and doing all other lawfully permitted acts to accomplish the foregoing purposes with the same legal force and effect as if executed by me.
- (f) <u>Exempt Inventions</u>. I understand that this Agreement does not require assignment of an Invention for which no equipment, supplies, facilities, resources, or trade secret information of the Company was used and which was developed entirely by me on my own time, unless the invention relates, (i) directly to the business of the Company, or (ii) to the Company's actual or demonstrably anticipated research or development. However, I will disclose to the Company any Inventions I claim are exempt, as required by paragraph (c), above, in order to permit the Company to determine such issues as may arise. Such disclosure shall be received in confidence by the Company.
- 6. <u>Prior Inventions.</u> As a matter of record I attach hereto as Exhibit A a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company which have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment with the Company, that I desire to remove from the operation of this Agreement, and I covenant that such list is complete. If no such list is attached to this Agreement, I represent that I have no such inventions and improvements at the time of my signing this Agreement.
- 7. Other Business Activities. So that the Company may be aware of the extent of any other demands upon my time and attention, I will disclose to the Company (such disclosure to be held in confidence by the Company) the nature and scope of any other business activity in which I am or become engaged during the term of my employment. During the term of my employment, I will not engage in any business activity or employment which is in competition with, or is related to, the Company's business or its actual or demonstrably anticipated research and development, or that will affect in any manner my ability to perform fully all of my duties and responsibilities for the Company.
- 8. <u>Non-Interference and Non-Solicitation of Employees, Customers and Others</u>. I will not now or at any time in the future disrupt, damage, impair or interfere with the business of the Company, whether by way of interfering with or raiding its employees, disrupting its relationships with customers, agents, vendors, distributors or representatives, or otherwise. During my employment with the Company and for eighteen (18) months thereafter, I will not directly or indirectly induce, encourage or solicit any employee of the Company to leave the Company for any reason, unless specifically requested to take such action in writing by the Company.

- 9. <u>Non-Competition During and After Employment.</u> I agree that the time and activity restrictions in this paragraph are wholly necessary and are reasonable to protect the legitimate business interests of the Company. During my employment with the Company or at any time within a period of one (1) year after the termination of my employment (whether the termination is by me or the Company), I will not directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity, compete with the Company in the business of developing or commercializing pulmonary surfactants.
- Obligations to Former Employers. I represent that my execution of this Agreement, my employment with the Company, and my performance of my duties and proposed duties to the Company will not violate any obligations or agreements I have, or may have, with any former employer or any other third party, including any obligations and agreements requiring me not to compete or to keep confidential any proprietary or confidential information. I have not entered into, and I will not enter into, any agreement which conflicts with this Agreement or that would, if performed by me, cause me to breach this Agreement. I further represent that I have no knowledge of any pending or threatened litigation to which the Company may become a party by virtue of my association with the Company. I further agree to immediately inform the Company of any such pending or threatened litigation should it come to my attention during the course of my employment. I also agree that I provided to the Company for its inspection before I signed this Agreement all confidentiality, non-compete, non-solicitation, and all other employment-related agreements that I am party to or which involve me.
- 11. <u>Confidential Information of, and Agreements with, Former Employers.</u> In the course of performing my duties to the Company, I will not utilize any trade secrets, proprietary or confidential information of or regarding any former employer or business affiliate, nor violate any written or oral, express or implied agreement with any former employer or business affiliate.
- 12. <u>United States Government Obligations.</u> I acknowledge that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to be bound by all such obligations and restrictions which are made known to me and to take all action necessary to discharge the obligations of the Company under such agreements.
- 13. Remedies. I acknowledge that my failure to comply with, or my breach of, any of the terms and conditions of this Agreement shall irreparably harm the Company, and that money damages would not adequately compensate the Company for this harm. Accordingly, I acknowledge that in the event of a threatened or actual breach by me of any provision of this Agreement, in addition to any other remedies the Company may have at law, the Company shall be entitled to equitable relief in the form of specific performance, temporary restraining order, temporary or permanent injunction or any other equitable remedy then available, without requiring the Company to post any bond. I agree that nothing herein contained shall be construed as prohibiting the Company from pursuing any other remedies available to it for such threatened or actual breach, including money damages, and I agree that the Company shall be entitled to recover from me any attorney's fees it incurs in enforcing the terms of this Agreement.

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

## 15. <u>Miscellaneous</u>.

- (a) <u>Reformation and Severability</u>. If any provision of this Agreement is held to be invalid or unenforceable under applicable law, such provision shall be reformed and/or construed, if possible, to be enforceable under applicable law; otherwise, such provision shall be excluded from this Agreement and the balance of the Agreement shall remain fully enforceable and valid in accordance with its terms.
- (b) No Waiver. No delay or omission by the Company in exercising any right hereunder will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.
- (c) <u>Reassignment</u>. I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employment I may be transferred, without the necessity that this Agreement be reassigned at the time of such transfer.
- (d) <u>Applicable Law</u>. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania (but not the law or principles of conflict of laws), and the parties submit to the jurisdiction of the courts of Pennsylvania.
- (e) <u>Effective Date</u>. This Agreement shall be effective as of the first day of my employment by the Company, shall be binding upon me, my heirs, executors, assigns and administrators, and shall inure to the benefit of the Company, its successors and assigns.
- (f) <u>Entire Agreement</u>. This Agreement contains the entire agreement of the parties relating to the subject matter herein, and may not be waived, changed, extended or discharged except by an agreement in writing signed by both parties.

questions regarding the effect of this Agreement or the meaning of its terms answered to my satisfaction, and, intending to be legally bound hereby, I freely and voluntarily sign this Agreement.				
Accepted and Agreed to:	Discovery Laboratories, Inc.			
Name:	Ву:			
Date:	Name:			
SS#:	Title:			
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provisions of this Agreement, that I have had the opportunity to consult with an attorney and to discuss this Agreement with an attorney, that I have had any

ACKNOWLEDGEMENT. I acknowledge and agree that I have fully read and that I understand all of the terms and

# EXHIBIT A

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

Attn:		
		The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by Discovery Company") that have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment lesire to remove from the operation of the Company's Proprietary Information and Inventions, Non-Solicitation and Non-Competition
		No inventions or improvements.
		See below: Any and all inventions regarding
		Additional sheets attached.
	2.	I propose to bring to my employment the following materials and documents of a former employer:
		No materials or documents.
		See below:
Date		

#### **CERTIFICATIONS**

## I, John G. Cooper, certify that:

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

Date: May 12, 2014

/s/ John G. Cooper

John G. Cooper

President and Chief Executive Officer

#### **CERTIFICATIONS**

## I, John Tattory, certify that:

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

Date: May 12, 2014

/s/ John Tattory

John Tattory Senior Vice President and Chief Financial Officer

## **CERTIFICATIONS**

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that, to his knowledge, the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2014 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2014

# /s/ John G. Cooper

John G. Cooper

President and Chief Executive Officer

## /s/ John Tattory

John Tattory

Senior Vice President and Chief Financial Officer

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

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