
**SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

August 5, 2014

Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-26422

(Commission File Number)

94-3171943

(IRS Employer Identification Number)

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

(215) 488-9300

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On August 5, 2014, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended June 30, 2014, and providing a business update. The press release is attached as Exhibit 99.1 hereto.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 hereto relating to the announcement of the results of operations for the quarter ended June 30, 2014 and all other matters except for those discussed under Item 8.01 below shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filings.

Item 7.01. Regulation FD Disclosure

On August 5, 2014, the Company issued a press release and will host a conference call highlighting the results of operations for the quarter ended June 30, 2014 and providing updates on its SURFAXIN® commercial introduction and its AEROSURF® development program. The updates include:

The Company continues its efforts regarding the commercial introduction of SURFAXIN and is focused on securing formulary acceptance or restricted use allowance with hospitals that it considers to be influential centers of excellence with strong reputations in the neonatal community, as well as affiliated and regional hospitals. To date, the Company has achieved formulary acceptance or restricted use in a total of 15 neonatal critical care facilities. Although not a predictor of revenues, the Company believes that formulary acceptance generally is a prerequisite for a hospital to purchase drug product. Although formulary acceptance does not represent confirmation that a hospital will purchase drug product, the number of hospitals that accept SURFAXIN on formulary are indicative of progress made. The Company is encouraged by the fact that, to date, more than 75% of hospitals that have completed the review process for SURFAXIN have accepted it on formulary.

The ongoing AEROSURF phase 2 clinical program consists of phase 2a, which is designed to assess safety and tolerability of aerosolized KL₄ surfactant delivered to premature infants receiving nCPAP, and phase 2b, which is designed to determine the optimal dose and provide an estimate of the size of the clinical effect of treatment and define the expected efficacy margin. The Company remains on track to complete this phase 2 clinical program in the second half of 2015.

The Company reported that, to date, its capillary aerosol generator (CAG) has been operating as expected, for the periods required, hospitals have indicated that aerosol administration has been incorporated well into the work flow of the neonatal intensive care units (NICUs), and clinicians have generally reported a positive experience with the device. The Company is pleased with the physiologic data and clinical observations thus far, and that no concerning safety signals have been observed to date.

Patient enrollment during the second quarter was slower than expected, but that enrollment rates had returned to expected levels in the third quarter. In addition, the Company has reviewed data from the four clinical study sites that indicate that the number of 33-to-34 week gestational age (GA) infants who could meet eligibility requirements and potentially benefit from aerosolized KL₄ surfactant is larger than estimated using prior research. Based on this encouraging data, the Company has amended its trial protocol to increase the gestational age inclusion criteria from 29-to-32 weeks GA to 29-to-34 weeks GA, and expanded the number of patients in the study to 42. The Company now anticipates phase 2a data in the fourth quarter of 2014.

The Company ended the second quarter with \$65.5 million in cash and cash equivalents. For the third quarter of 2014, the Company anticipates operating cash outflows of approximately \$11 million, before taking into account any financing activities. At the present time, the Company anticipates that it will have sufficient cash available to fund future operations and debt service obligations through the third quarter of 2015.

Disclosure Notice

The information in the Press Release, conference call and this Current Report on Form 8-K includes or is expected to include certain "forward-looking" statements relating, among other things, to the Company's plans regarding the commercial introduction of SURFAXIN drug product, the conduct of its initial AEROSURF phase 2a clinical trial, and plans regarding the design and goals for its AEROSURF phase 2 clinical program generally. These and other similar statements are forward-looking and are or will be made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. While the Company currently believes that it will succeed in meeting the timelines outlined in the Press Release, conference call and this Form 8-K, such forward-looking statements are subject to a variety of risks and uncertainties that could cause actual results to be materially different. These risks and uncertainties include, but are not limited to, risks outlined in the following risk factors, as well as those risks and uncertainties described in the Company's filings with the Securities and Exchange Commission, including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement in this Current Report on Form 8-K and related exhibits speaks only as of the date on which it is made. The Company assumes no obligation to update or revise any forward-looking statements.

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

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

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

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

- We may not achieve broad market acceptance of our other KL4 surfactant products, including AEROSURF, by physicians, respiratory therapists, nurses and other personnel in the NICU and elsewhere in the hospital, as well as patients, healthcare payers and others in the medical community in general, which could impair our ability to develop, and if approved, commercialize other KL4 surfactant products.
 - The market price of our stock could be adversely affected, which may make it more difficult to conduct equity financing transactions, attract strategic partners or enter into collaboration or other agreements and maintain compliance with the listing requirements of The Nasdaq Capital Market.
 - We may be unable to pay our debt service. We have pledged substantially all of our assets to secure our obligations under a \$30 million loan (Deerfield Loan) from affiliates of Deerfield Management Company, L.P. (Deerfield). If we were to fail in the future to make any required payment under the Deerfield Loan or fail to comply with the covenants contained in the facility agreement and other related agreements, we would be in default regarding that indebtedness, which would enable the lenders to foreclose on the assets securing such debt and could result in the acceleration of the payment obligations under all or a portion of our consolidated indebtedness.
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Our long-term manufacturing strategy includes potentially manufacturing our KL4 surfactant at our Totowa Facility, and relying on third parties to manufacture our approved products as well as our drug product and medical device candidates, all of which expose us to risks that may affect our ability to maintain supplies of our commercial products and/or delay our research and development activities, regulatory approval and commercialization of our drug product and medical device candidates.

We currently manufacture SURFAXIN at our manufacturing operations in Totowa, New Jersey (Totowa Facility), for which our lease is currently scheduled to expire in June 2015. We also expect to manufacture lyophilized KL4 surfactant, our CAG, WARMING CRADLE® and AFFECTAIR® devices, with CMOs. Our manufacturing plans could expose us to the following risks:

- We are currently in discussions with our landlord to potentially secure long-term utilization of that facility. We believe that our efforts to secure longer-term utilization of our Totowa Facility will be successful; however, if we are unable to succeed, we most likely will experience an interruption in supply of SURFAXIN drug product.
- In seeking to identify CMOs to manufacture products on our behalf, we may be unable to identify manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all, because the number of potential CMOs is limited and the FDA must approve any replacement CMO. This approval could require one or more pre-approval inspections as well as a potentially lengthy qualification process. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our approved products after receipt of FDA approval. This could take as long as 2 years to qualify and receive regulatory approval.
- We may implement a plan to execute a technology transfer of our manufacturing process to a CMO and, after investing significant time and resources, learn that the CMO we chose is unable to successfully complete the technology transfer and manufacture our products in accordance with our plan.
- CMOs might be unable to manufacture our products in the volume and to our specifications to meet our commercial, preclinical and clinical needs, or we may have difficulty scheduling the production of drug product and devices in a timely manner to meet our timing requirements.
- CMOs may not perform as agreed, or may not remain in the CMO business for a lengthy time, or may refuse to renew an expiring agreement as expected, or may fail to produce a sufficient supply to meet our commercial and/or clinical needs.
- CMOs are subject to ongoing periodic unannounced inspection by the FDA, international health authorities, registered Notified Bodies, the U. S. Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with current good manufacturing practices (cGMP) and/or quality system regulations (QSR) and other government regulations and corresponding foreign standards. We do not have control over a CMO's compliance with these regulations and standards.
- Should we desire to make our drug products and/or devices available outside the U.S. for commercial or clinical purposes, our CMOs would become subject to, and may not be able to comply with, corresponding cGMPs and QSRs of the various foreign regulators having jurisdiction over our activities abroad. Such failures could restrict our ability to execute our business strategies.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not have rights to, or may have to share, the intellectual property rights to any such innovation. We may be required to pay fees or other costs for access to such improvements.

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

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

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

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

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

In addition, if in our clinical trials we succeed in achieving our patient enrollment targets, our patients could suffer adverse medical events or side effects that are known to be associated with surfactant administration, such as a decrease in the oxygen level of the blood, or currently unknown to us. It is also possible that we, our AEROSURF Clinical Trial (ACT) Steering Committee, the Safety Review Committee (SRC), or the FDA could interrupt, delay or halt any one or more of our clinical trials for AEROSURF or any of our product candidates. If our ACT Steering Committee, the SRC, any regulator or we believe that study participants face unacceptable health risks, any one or more of our clinical trials could be suspended or terminated. In addition, clinical trials may be interrupted, delayed or halted, in whole or in part, for reasons other than health and safety concerns, including, among other things, matters related to the design of the study, drug availability, ACT Steering Committee and/or SRC recommendation, or business reasons.

In addition to our planned clinical program to support AEROSURF, in the future we also may initiate or support clinical trials evaluating other KL4 surfactant pipeline products. All of these clinical trials will be time-consuming and potentially costly. Should we fail to complete our clinical development programs or should such programs yield unacceptable results, such failures would have a material adverse effect on our business.

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

Our operations have consumed substantial amounts of cash since inception. As of June 30, 2014, we had cash and cash equivalents of approximately \$66 million and \$30 million of long-term debt under a secured loan with affiliates of Deerfield Management Company, L.P. Before any additional financings, including under our ATM Program, we anticipate that we will have sufficient cash available to support our current operations and debt service obligations through the third quarter of 2015.

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

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release dated August 5, 2014

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development, cash flows, future revenues, the timing of planned clinical trials or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement made by us in this Current Report on Form 8-K is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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 hereunto duly authorized.

Discovery Laboratories, Inc.

By: /s/ John G. Cooper

Name: John G. Cooper

Title: President and Chief Executive Officer

Date: August 5, 2014



Discovery Labs Reports Second Quarter 2014 Financial Results

WARRINGTON, PA — August 5, 2014 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today announced financial results for the second quarter ended June 30, 2014, as well as recent business updates. The Company will host a conference call today, August 5, 2014 at 9:00 AM ET to discuss the 2014 second quarter financial results and other business updates.

Financial update

- Reported an operating loss of \$10.9 million and net cash outflows before financing activities of \$10.4 million for the second quarter of 2014;
- Ended the second quarter of 2014 with cash and cash equivalents of \$65.6 million; and
- Awarded \$1.9 million Fast Track Small Business Innovation Research (SBIR) Grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the phase 2a clinical trial for AEROSURF®.

SURFAXIN® (lucinactant): SURFAXIN is the liquid dosage form of the Company's novel KL₄ surfactant and is the first FDA-approved synthetic, peptide-containing alternative to animal-derived surfactants. Currently, the Company is focused on securing formulary acceptance with hospitals that it considers to be influential centers of influence with strong reputations in the neonatal community, as well as affiliated and regional hospitals. To date, the Company achieved formulary acceptance or restricted use allowance in a total of 15 neonatal critical care facilities.

AEROSURF: The ongoing phase 2 clinical program for our investigational product AEROSURF consists of a phase 2a trial, which is designed to assess safety and tolerability of aerosolized KL₄ surfactant delivered to premature infants receiving nasal continuous positive airway pressure (nCPAP), and a phase 2b trial, which is designed to determine the optimal dose and define the expected efficacy margin. The Company remains on track to complete this phase 2 clinical program in the second half of 2015. During the second quarter, the Company noted slower-than-expected enrollment in the phase 2a trial, with enrollment rates improving to expected levels thus far in the third quarter. Additionally, data from our study sites indicate that the number of 33-to-34 week gestational age (GA) infants who could meet eligibility requirements and potentially benefit from aerosolized KL₄ surfactant is larger than indicated by prior research. Accordingly, the Company has amended its trial protocol to increase the gestational age inclusion criteria from 29-to-32 weeks GA to 29-to-34 weeks GA, and expanded the number of patients in the study to 42. The Company now anticipates phase 2a data in the fourth quarter of 2014.

“The second quarter of 2014 was one of tangible progress towards our goal to advance the treatment paradigm for infants born at risk of respiratory distress syndrome,” commented John G. Cooper, President and Chief Executive Officer at Discovery Labs. “SURFAXIN is the first step. Consistent with our measured approach, we are focused on formulary acceptance in hospitals, in-service training to assure that SURFAXIN is administered safely and consistently, and building relationships at key centers of influence. As we engage with these hospitals, we frequently hear of the desire for AEROSURF, which has the potential to address a significant unmet medical need, namely to reduce the rates of invasive endotracheal intubation and nCPAP failure, which can lead to poor medical outcomes. As we prepare for our phase 2b program later this year, we are encouraged by the great desire among the neonatal community to participate in this clinical program.”

Summary Financial Results for the Second Quarter Ended June 30, 2014

The Company reported a net loss of \$10.6 million (\$0.12 per basic share) on 85.1 million weighted-average common shares outstanding for the quarter ended June 30, 2014, compared to a net loss of \$8.6 million (\$0.18 per basic share) on 49.1 million weighted-average common shares outstanding for the comparable period in 2013. Included in the net loss is the change in fair value of certain common stock warrants that are classified as derivative liabilities, resulting in non-cash income of \$1.4 million and \$2.5 million for the quarters ended June 30, 2014 and 2013, respectively.

For the quarter ended June 30, 2014, the Company reported an operating loss of \$10.9 million compared to \$10.8 million for the comparable period in 2013.

During the second quarter of 2014, sales of SURFAXIN to the Company's specialty distributor were approximately \$114,000 and demand sales into hospitals were \$72,000. In accordance with the Company's revenue recognition policy, for the second quarter of 2014, the Company recognized \$42,000 in revenue for sales of SURFAXIN. The Company also recognized \$1.1 million in grant revenue under a \$1.9 million Fast Track SBIR Grant from the NHLBI of the NIH to provide support for the ongoing phase 2a clinical trial for AEROSURF. The remaining \$0.8 million available under the grant is expected to be received by the end of 2014.

Operating expenses for the second quarter ended June 30, 2014 were \$12.0 million compared to \$11.0 million for the comparable period in 2013. The increase in operating expenses was due to costs associated with (i) the AEROSURF phase 2a clinical trial; (ii) initiating the manufacture of capillary aerosol generator (CAG) devices for use in our anticipated AEROSURF phase 2b program; and, (iii) increased investments in our medical affairs capabilities and programs to communicate the attributes of SURFAXIN and AEROSURF to the neonatal community in the United States. Additionally, operating expenses in 2013 included \$1.7 million in investments to support the initiation of the AEROSURF phase 2 program, including the design and development, with the assistance of the Battelle Memorial Institute, of a clinic-ready CAG device and the technology transfer of the Company's lyophilized KL4 surfactant manufacturing process to a contract manufacturing organization (CMO). Both of these projects were successfully concluded in 2013.

Other expense for the quarter ended June 30, 2014 was \$1.1 million which represents interest expense related to long-term debt. Of the \$1.1 million, \$0.6 million is cash interest expense and \$0.5 million is non-cash amortization of the debt discount.

Net cash outflows before financing activities for the quarter ended June 30, 2014 were \$10.4 million.

As of June 30, 2014, the Company had cash and cash equivalents of \$65.6 million. For the third quarter of 2014, the Company anticipates operating cash outflows before financing activities of approximately \$11 million.

As of June 30, 2014, the Company had \$30 million of long-term debt with principal payable in three equal annual installments beginning in 2017, subject to a one year deferral of the amounts due in each of 2017 and 2018 if certain financial milestones are achieved.

As of June 30, 2014, the Company reported a common stock warrant liability of \$3.2 million, predominantly related to five-year warrants issued in February 2011. These warrants are not subject to cash settlement, but they have been classified as derivative liabilities in accordance with generally accepted accounting principles because they contain anti-dilution provisions that adjust the exercise price of the warrants in certain circumstances.

The Company had 85.2 million and 84.6 million shares of common stock outstanding as of June 30, 2014 and December 31, 2013, respectively.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 to be filed with the Securities and Exchange Commission on or before August 11, 2014, which includes further detail on the above-referenced transactions and the Company's business plans and operations, financial condition and results of operations.

Conference Call and Audio Webcast Details

The Company will host a live teleconference and webcast at 9:00 a.m. Eastern Time today. During the conference call, Discovery Labs' management will discuss the 2014 second quarter financial results along with other business updates.

The press release and the live webcast of the conference call will be available via Discovery Labs' corporate website at www.discoverylabs.com. The webcast will be made available on the events page. An audio archive will be available after the call at the same address until Tuesday, September 2, 2014.

To participate in the live conference call, please dial (877) 870-4263 (domestic) or (412) 317-0790 (international). After placing the call, please ask to be joined into the Discovery Labs conference call. The conference call replay number is (877) 344-7529 (domestic) or (412) 317-0088 (international); please use 10049810 as the replay passcode.

About AEROSURF®

AEROSURF is a novel investigational drug-device combination product being developed to deliver Discovery Labs' KL4 surfactant in aerosolized form to premature infants with respiratory distress syndrome (RDS). AEROSURF could potentially allow for the administration of KL4 surfactant to premature infants without invasive endotracheal intubation, and may enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated. Discovery Labs has initiated a phase 2a clinical study to evaluate the safety and tolerability of aerosolized KL4 surfactant drug product administered in escalating inhaled doses in premature infants 29 to 34 weeks gestational age who are receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to infants receiving nCPAP alone.

About Discovery Labs

Discovery Laboratories, Inc. is a specialty biotechnology company focused on advancing a new standard in respiratory critical care. Discovery Labs' technology platform includes its novel proprietary KL4 surfactant, a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant, and its proprietary drug delivery technologies being developed to enable efficient delivery of aerosolized KL4 surfactant. Discovery Labs' strategy is initially focused on neonatology and improving the management of respiratory distress syndrome (RDS) in premature infants. Discovery Labs believes that its RDS product portfolio, including AEROSURF, if approved, has the potential to become the new standard of care for RDS and, over time, enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated.

For more information, please visit the Company's website at www.Discoverylabs.com.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results, including projections of future cash balances and anticipated cash outflows, to differ materially from the statements made. Examples of such risks and uncertainties include: risks that Discovery Labs will be unable to secure significant additional capital as needed, or to access debt or equity financings, which could result in substantial equity dilution, and may be unable in a timely manner, if at all, to identify potential strategic partners to support product development and, if approved, commercialize products in markets outside the U.S.; risks related to development programs, including the AEROSURF development program, which may involve time-consuming and expensive pre-clinical studies and clinical trials that may be subject to potentially significant delays or regulatory holds, or fail; risks relating to efforts to commercialize SURFAXIN, including (1) whether Discovery Labs' commercial and medical affairs organizations will succeed in introducing SURFAXIN, (2) whether SURFAXIN will be approved by hospitals and will gain market acceptance and be preferred by healthcare providers over current products, and (3) whether SURFAXIN will generate revenues sufficient to fund Discovery Labs' research and development activities and support its operations, and (4) whether Discovery Labs will be successful in implementing its long-term manufacturing strategy to assure continuity of SURFAXIN commercial drug product supply, which may affect its ability to maintain sufficient supplies of SURFAXIN commercial drug product; risks related to technology transfers to contract manufacturers and problems or delays encountered by Discovery Labs, contract manufacturers or suppliers in manufacturing drug products, drug substances, aerosol-conducting airway connectors, CAG devices and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the FDA or other regulatory authorities may not agree with Discovery Labs on matters raised during regulatory reviews, may require significant additional activities, or may not accept or may withhold or delay consideration of applications, or may not approve or may limit approval of Discovery Labs' products, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals; and other risks, including those related to (1) continued compliance with The Nasdaq Capital Market® listing requirements, (2) Discovery Labs' efforts to maintain and protect the patents and licenses related to its products, (3) whether it or its strategic partners will be able to attract and retain qualified personnel, (4) other companies' competing products, (5) legal proceedings, and (6) health care reform; and other risks and uncertainties described in Discovery Labs' filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Contact Information:

John Tattory, Senior Vice President and Chief Financial Officer: 215.488.9418 or jtattory@discoverylabs.com

Will Roberts, Vice President, Investor Relations and Corporate Communication: 215.488.9489 or wroberts@discoverylabs.com

Discovery Laboratories, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30	
	(unaudited)		(unaudited)	
	2014	2013	2014	2013
Revenues:				
Product sales	\$ 42	\$ –	\$ 70	\$ –
Grant revenue	1,051	182	1,054	254
Total Revenue	1,093	182	1,124	254
Operating expenses: (1)				
Cost of product sales	731	–	1,512	–
Research and development	6,858	6,863	12,448	15,335
Selling, general and administrative	4,446	4,129	8,869	8,349
Total expenses	12,035	10,992	22,829	23,684
Operating loss	(10,942)	(10,810)	(21,705)	(23,430)
Change in fair value of common stock warrant liability (1)	1,448	2,525	1,826	2,686
Other income/(expense), net	(1,129)	(342)	(2,220)	(519)
Net loss	\$ (10,623)	\$ (8,627)	\$ (22,099)	\$ (21,263)
Net loss per common share:				
Basic	\$ (0.12)	\$ (0.18)	\$ (0.26)	\$ (0.46)
Diluted	\$ (0.14)	\$ (0.22)	\$ (0.28)	\$ (0.50)
Weighted avg. common shares outstanding:				
Basic	85,061	49,135	84,766	46,411
Diluted	85,882	49,866	86,111	47,773

(1) Material non-cash items include the change in fair value of certain outstanding warrants accounted for as derivative liabilities, and in operating expenses, depreciation and stock-based compensation. For the three months ended June 30, 2014 and 2013, the charges for depreciation and stock-based compensation were \$1.0 million (\$0.5 million in R&D and \$0.5 million in S,G&A) and \$0.8 million (\$0.4 million in R&D and \$0.4 million in S,G&A), respectively. For the six months ended June 30, 2014 and 2013, the charges for depreciation and stock-based compensation were \$1.8 million (\$0.9 million in R&D and \$0.9 million in S,G&A) and \$1.3 million (\$0.7 million in R&D and \$0.6 million in S,G&A), respectively.

Discovery Laboratories, Inc.
Condensed Consolidated Balance Sheet
(in thousands, except per share data)

	June 30,	December 31,
	2014	2013
	(Unaudited)	
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 65,557	86,283
Accounts receivable	41	67
Inventory	443	112
Prepaid expenses and other current assets	443	777
Total current assets	66,484	87,239
Property and equipment, net	2,178	1,656
Restricted cash	325	325
Other assets	487	97
Total Assets	69,474	89,317

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:		
Accounts payable and accrued liabilities	7,458	6,218
Deferred revenue	105	139
Common stock warrant liability	3,224	5,425
Equipment loans, current portion	75	73
Total Current Liabilities	10,862	11,855
Long-Term Liabilities:		
Long-term debt, net of discount of \$10,736 at June 30, 2014 and \$11,646 at December 31, 2013, respectively	19,264	18,354
Equipment loan, non-current portion	28	69
Other liabilities	114	538
Total Liabilities	30,268	30,816

Stockholders' Equity:	39,206	58,501
Total Liabilities and Stockholders' Equity	<u>69,474</u>	<u>89,317</u>
