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

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**FORM 8-K**

**CURRENT REPORT**

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

**November 12, 2013**

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 November 12, 2013, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the year and quarter ended September 30, 2013, and providing an update on its development programs. 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 year and quarter ended September 30, 2013 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 8.01. Other Events.**

As set forth in the press release referred to above, for the fourth quarter of 2013, the Company anticipates net cash outflows of approximately \$10.5 million, before financing activities and before taking into account the anticipated advance under the Company’s secured lending facility with Deerfield Management Company, L.P. The press release also provides certain program updates relating to SURFAXIN® and the Company’s AEROSURF® development program.

Subject to the note relating to the press release contained in Item 2.02 of this Current Report on Form 8-K, the press release is attached as Exhibit 99.1 hereto.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

[99.1](#) Press release dated November 12, 2013

**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 outflows, 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.

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**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: November 12, 2013

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## Discovery Labs Reports Third Quarter 2013 Financial Results

*Conference Call Wednesday, November 13, 2013 at 10:00 a.m. ET*

**WARRINGTON, PA — November 12, 2013** — 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 third quarter ended September 30, 2013, as well as recent business updates. The Company will host a conference call Wednesday morning, November 13, 2013 at 10:00 AM ET. Conference call details are below.

Key updates include:

- **SURFAXIN®**: On October 4, 2013, the U.S. Food and Drug Administration (FDA) agreed to the Company's updated product specifications for SURFAXIN (lucinactant) Intratracheal Suspension. SURFAXIN is the first FDA-approved synthetic, peptide containing surfactant available for the prevention of respiratory distress syndrome (RDS) in premature infants and the only approved alternative to animal-derived surfactants currently available today in the U.S. On November 8, 2013, the Company announced that it has initiated the commercial introduction of SURFAXIN in the U.S.
- **AEROSURF®**: In October 2013, the Company submitted an investigational new drug (IND) application to the FDA to initiate its AEROSURF phase 2 clinical program. The FDA has completed its review and cleared the IND, and the Company can now proceed with its phase 2 clinical program. AEROSURF is a novel investigational drug-device combination product being developed to deliver the Company's KL4 surfactant in aerosolized form to premature infants with RDS. AEROSURF could potentially provide neonatologists with the ability to avoid invasive procedures and thereby enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy and currently are not treated. The Company anticipates results from the first phase of its AEROSURF phase 2 clinical program in mid-2014.
- **Financial Update**: As of September 30, 2013, the Company reported cash and cash equivalents of \$21.2 million. In November 2013, the Company completed a public offering of its common stock that resulted in net proceeds, including amounts expected from an over-allotment recently exercised by the underwriters, of approximately \$54 million. Additionally, with the initiation of the commercial launch of SURFAXIN, the Company became eligible under its secured loan facility with Deerfield Management Co., L.P. (Deerfield) to receive an additional advance of \$20 million, which is expected in early December 2013.

"With the commercial introduction of SURFAXIN, initiation of our clinical program for AEROSURF and our strengthened financial position, we are a much stronger company and better positioned to implement our business plan and achieve our vision of advancing a new standard of care for premature infants with RDS." commented John G. Cooper, President and Chief Executive Officer at Discovery Labs.

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## Summary Financial Results for the Third Quarter Ended September 30, 2013

For the quarter ended September 30, 2013, the Company reported a net loss of \$12.2 million (\$0.22 basic net loss per share) on 54.8 million weighted-average common shares outstanding, compared to a net loss of \$13.3 million (\$0.31 basic net loss per share) on 43.4 million weighted-average common shares outstanding for the same period in 2012. Included in the net loss is the change in fair value of certain common stock warrants that are classified as derivative liabilities, resulting in a non-cash loss of \$1.1 million and \$3.3 million in 2013 and 2012, respectively.

The Company reported an operating loss of \$10.8 million for the quarter ended September 30, 2013 compared to an operating loss of \$10.0 million for the same period in 2012. Net cash outflows before financing activities for the quarter ended September 30, 2013 were \$10.1 million compared to \$9.9 million for the same period in 2012. The operating loss for the quarter ended September 30, 2013 includes a \$1.3 million investment to prepare for the AEROSURF phase 2 clinical trials.

As of September 30, 2013, the Company had cash and cash equivalents of \$21.2 million. On November 5, 2013, the Company completed a public offering of 25 million shares of common stock at a price of \$2.00 per share, resulting in net proceeds to the Company (after underwriting discount and anticipated expenses) of approximately \$46.8 million. The Company also granted the underwriters a 30-day option to purchase up to an additional 3.75 million shares of common stock at an offering price of \$2.00 to cover over-allotments, if any. On November 8, 2013, the underwriter notified the Company that it has exercised its over-allotment option to purchase 3.75 million additional shares of common stock. The exercise of the option is expected to close on or about November 14, 2013 and result in net proceeds (after underwriting discount) of approximately \$7.1 million.

Additionally, with the commercial introduction of SURFAXIN, the Company became eligible under its \$30 million secured loan facility with Deerfield to receive the final \$20 million advance, which is expected on or about December 3, 2013. The initial \$10 million was advanced in February 2013 upon execution of the facility agreement. In connection with the \$20 million advance, Deerfield will receive a transaction fee equal to 1.5% of the advance, and warrants to purchase approximately 4.7 million shares of common stock at an exercise price of \$2.81 per share.

In October 2013, the Company initiated an offering under its at-the-market (ATM) Program with Stifel, Nicolaus & Company, Incorporated and issued 713,920 shares of common stock at an average price per share of \$2.75, resulting in net proceeds (after a 3% commission) of approximately \$1.9 million. Following this offering, approximately \$23.1 million remains available under the Company's ATM Program.

For the fourth quarter of 2013, the Company anticipates operating cash outflows before financing activities of \$10.5 million, and approximately \$85 million in cash and cash equivalents at December 31, 2013.

As of September 30, 2013, the Company reported a common stock warrant liability of \$4.7 million, predominantly related to five-year warrants issued in February 2011. These warrants are not subject to cash settlement; however, 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 54.9 and 43.7 million shares of common stock outstanding as of September 30, 2013 and December 31, 2012, respectively. The Company currently has 80.7 million shares of common stock outstanding, not including 3.75 million shares to be issued upon closing of underwriters' over-allotment option.

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Readers are referred to, and encouraged to read in their entirety the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 filed with the Securities and Exchange Commission, 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**

Discovery Labs will hold a conference call and audio webcast on Wednesday, November 13, 2013 at 10:00 AM ET to discuss the foregoing. To access the conference call and participate in the question-and-answer session, the number for domestic callers is (877) 870-4263 and for international callers (412) 317-0790. The conference call replay number is (877) 344-7529 or (412) 317-0088. The passcode for the replay is 10036729.

The audio webcast of the conference call will be available at <http://bit.ly/1962IVM> and the Discovery Labs website at [www.discoverylabs.com](http://www.discoverylabs.com). It is recommended that participants log onto the audio webcast at least 15 minutes prior to the call. A replay of the audio webcast will be available after the call at the Company's website.

#### **About SURFAXIN®**

The U.S. Food and Drug Administration (FDA) approved SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants who are at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal derived surfactants.

#### **IMPORTANT SAFETY INFORMATION**

SURFAXIN is intended for intratracheal use only. The administration of exogenous surfactants, including SURFAXIN, can rapidly affect oxygenation and lung compliance. SURFAXIN should be administered only by clinicians trained and experienced with intubation, ventilator management, and general care of premature infants in a highly supervised clinical setting. Infants receiving SURFAXIN should receive frequent clinical assessments so that oxygen and ventilatory support can be modified to respond to changes in respiratory status.

Most common adverse reactions associated with the use of SURFAXIN are endotracheal tube reflux, pallor, endotracheal tube obstruction, and need for dose interruption. During SURFAXIN administration, if bradycardia, oxygen desaturation, endotracheal tube reflux, or airway obstruction occurs, administration should be interrupted and the infant's clinical condition assessed and stabilized.

SURFAXIN is not indicated for use in acute respiratory distress syndrome (ARDS).

For more information about SURFAXIN, please visit [www.surfaxin.com](http://www.surfaxin.com).

#### **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.

#### **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 and other inhaled therapies. 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 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.

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For more information, please visit the Company's website at [www.Discoverylabs.com](http://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 relating to efforts to commercialize SURFAXIN and AFECTAIR, including (1) whether Discovery Labs' commercial and medical affairs organizations will succeed in introducing the products, (2) whether the products will be approved by hospitals and will gain market acceptance and be preferred by healthcare providers over current products, (3) whether the products will generate revenues sufficient to fund Discovery Labs' research and development activities and support its operations, and (4) whether Discovery Labs will successfully develop a planned second vial size for SURFAXIN and follow-on AFECTAIR devices; risks related to development programs, including in particular the AEROSURF development program, including time-consuming and expensive pre-clinical studies and clinical trials, which may be subject to potentially significant delays or regulatory holds, or fail; risks that Discovery Labs will be unable to secure significant additional capital as needed, 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., or to access debt or equity financings, which could result in substantial equity dilution; 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; 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, (3) other companies' competing products, (3) legal proceedings, and (4) 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:**

#### **Company**

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#### **Investor Relations**

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## Condensed Consolidated Statement of Operations

(in thousands, except per share data)

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30 (unaudited)	
	2013	2012	2013	2012
Revenue from collaborative arrangement and grants	\$ 60	\$ –	\$ 315	\$ –
Operating expenses: <sup>(1)</sup>				
Research and development	6,574	5,743	21,909	15,482
Selling, general and administrative	4,299	4,255	12,648	9,912
Total expenses	10,873	9,998	34,557	25,394
Operating loss	(10,813)	(9,998)	(34,242)	(25,394)
Change in fair value of common stock warrant liability	(1,059)	(3,309)	1,627	(5,063)
Interest and other income / (expense), net	(352)	(39)	(871)	(43)
Net loss	\$ (12,224)	\$ (13,346)	\$ (33,486)	\$ (30,500)
Net loss per common share:				
Basic	\$ (0.22)	\$ (0.31)	\$ (0.68)	\$ (0.80)
Diluted	\$ (0.22)	\$ (0.31)	\$ (0.69)	\$ (0.80)
Weighted avg. common shares outstanding:				
Basic	54,792	43,444	49,235	38,061
Diluted	54,792	43,444	50,377	38,061

(1) Includes non-cash charges for depreciation and stock-based compensation of \$0.8 million (\$0.4 million in R&D and \$0.4 million in SG&A) for each of the three months ended September 30, 2013 and 2012; and for the nine months ended September 30, 2013 and 2012, \$2.1 million (\$1.1 million in R&D and \$1.0 million in SG&A) and \$2.1 million (\$1.2 million in R&D and \$0.9 million in SG&A), respectively.

### Discovery Laboratories, Inc Condensed Consolidated Balance Sheets (in thousands)

	September 30, 2013 (Unaudited)	December 31, 2012
<b><u>ASSETS</u></b>		
Current Assets:		
Cash and cash equivalents	\$ 21,177	\$ 26,892
Inventory	117	195
Prepaid expenses and other current assets	418	719
Total current assets	21,712	27,806
Property and equipment, net	1,417	1,737
Restricted cash and other assets	502	400
Total Assets	\$ 23,631	\$ 29,943
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current Liabilities:		
Accounts payable	\$ 1,489	\$ 1,166
Accrued expenses	5,071	4,159
Common stock warrant liability	4,678	6,305
Equipment loan and capitalized leases, current portion	72	69
Total Current Liabilities	11,310	11,699
Long-Term Liabilities:		
Long-term debt, net of discount of \$3.7 million at September 30, 2013 and \$0 at December 31, 2012, respectively	6,326	–
Equipment loan, non-current portion & other liabilities	520	591
Total Liabilities	18,156	12,290
Stockholders' Equity:	5,475	17,653
Total Liabilities and Stockholders' Equity	\$ 23,631	\$ 29,943