

**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**

**March 13, 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 March 13, 2013, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the year and quarter ended December 31, 2012, 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 December 31, 2012 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.**

On March 13, 2013, the Company issued a press release highlighting the results of operations for the year and quarter ended December 31, 2012 and providing an update on its development programs. The Company noted that it anticipates the initiation of its planned Phase 2 clinical program for AEROSURF® in the fourth quarter of 2013. In preparation, the Company noted that it is working to complete the ongoing technology transfer of its manufacturing process for a lyophilized dosage form of its KL4 surfactant to a contract manufacturing organization, and that it is progressing with third-party medical device experts to optimize the design of its capillary aerosol generator.

For the first quarter of 2013, the Company anticipates operating cash outflows of approximately \$10.5 million, before taking into account financing activities. The Company affirms the guidance previously provided to investors, as follows: the Company anticipates that revenues from the sales of SURFAXIN® in the first 12 months of sales will be approximately \$8 million to \$10 million, in the fourth year of sales, approximately \$40 million to \$50 million, and in the seventh year of sales, approximately \$100 million. In addition, the Company also anticipates that revenues from the sales of AFECTAIR® in the first 12 months of sales following completion of the user experience program will be approximately \$0.5 million to \$1.0 million.

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

(d) Exhibits

[99.1](#) Press release dated March 13, 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: March 13, 2013

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### Discovery Labs Reports Fourth Quarter 2012 Financial Results

**Warrington, PA — March 13, 2012** — Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today reports financial results for the fourth quarter ended December 31, 2012 and also provides certain program updates. The Company will host a conference call this morning at 10:00 AM ET. Conference call details are below.

Selected Financial Information (further details provided in the summary financial results below):

- For the fourth quarter of 2012, the Company reported an operating loss of \$12.4 million. Excluding a one-time charge of \$2.0 million, the operating loss was \$10.4 million. Net cash outflows for the quarter were \$9.2 million.
- As of December 31, 2012, the Company had cash and cash equivalents of \$26.9 million.
- In February 2013, the Company entered into two agreements that, collectively, may provide access to up to \$55 million additional financing; a \$30 million secured loan facility with Deerfield Management Company, L.P. (Deerfield); and an at-the-market equity sales program (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel), under which the Company may, at its discretion, from time to time, sell up to a maximum of \$25 million of its shares of common stock to support its business plans.

“We believe that our RDS product portfolio has the potential to become the new standard of care for RDS and, over time, significantly expand the worldwide surfactant market. With our recent financing transactions, we have strengthened the financial position of our Company and continue to advance our key priorities,” commented John G. Cooper, President and Chief Executive Officer at Discovery Labs. “As we anticipate the availability of SURFAXIN<sup>®</sup> drug product in the second quarter, our specialty field force has been focused primarily on securing hospital formulary acceptance for SURFAXIN, as well as adoption of AFECTAIR<sup>®</sup>. We continue to make progress on our AEROSURF<sup>®</sup> development program and plan to initiate our phase 2 clinical program in the fourth quarter of 2013.”

Selected Program Updates:

**SURFAXIN:** SURFAXIN (lucinactant) intratracheal suspension is the first synthetic, peptide-containing surfactant approved by the Food and Drug Administration (FDA) and provides healthcare practitioners an alternative to animal-derived surfactants to prevent respiratory distress syndrome (RDS) in premature infants. In the third quarter of 2012, the Company determined that one of the analytical chemistry methods used to assess SURFAXIN drug product conformance to specifications required improvement and that an update to product specifications was needed. As a result, the Company delayed the commercial launch of SURFAXIN. The Company proactively communicated these findings to the FDA, improved and validated the analytical chemistry method, and submitted updated product specifications to the FDA. The planned activities remain on track, and, pending confirmation from the FDA regarding the updated product specifications, the Company believes that SURFAXIN will be available for commercial sale in the second quarter of 2013.

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**AEROSURE:** The Company is developing AEROSURF as a drug/device combination product to potentially allow neonatal practitioners to deliver aerosolized KL4 surfactant to premature infants without the need for invasive endotracheal intubation. If efforts are successful, AEROSURF could enable the treatment of a significantly greater number of premature infants at risk for RDS. The Company is progressing with third-party medical device experts to optimize the design of its capillary aerosol generator (CAG). Additionally, the Company plans to use a lyophilized dosage form of KL4 surfactant in the AEROSURF program and is working to complete the ongoing technology transfer of the manufacturing process to a contract manufacturing organization (CMO) that has expertise in lyophilization. The Company anticipates completion of both of these activities in mid-2013, facilitating the initiation of the planned phase 2 clinical program in the fourth quarter of 2013.

**AFECTAIR:** The Company is beginning the commercial introduction of its AFECTAIR aerosol-conducting airway connector for infants receiving aerosolized medication in neonatal or pediatric intensive care units with a user experience program that is being conducted in select U.S. critical care centers that represent approximately ten percent (10%) of target institutions. This initial phase is intended to facilitate peer-to-peer exchange among physicians and respiratory therapists and enable discussion about the potential advantages and proper utilization of this novel device. Upon anticipated completion of this phase in the second quarter of 2013, the Company will initiate a broader introduction of AFECTAIR.

#### Summary Financial Results for the Fourth Quarter ended December 31, 2012

For the quarter ended December 31, 2012, the Company reported a net loss of \$6.8 million (\$0.16 per share) on 43.5 million weighted-average common shares outstanding, compared to a net loss of \$4.3 million (\$0.18 per share) on 24.3 million weighted-average common shares outstanding for the comparable period in 2011. 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 \$5.6 million and \$1.6 million for the quarters ended December 31, 2012 and 2011, respectively.

The Company reported an operating loss of \$12.4 million for the quarter ended December 31, 2012 compared to an operating loss of \$5.9 million for the comparable period in 2011. The increase is primarily due to (i) investments in the Company's specialty commercial and medical affairs organizations, including a field sales force, national accounts and medical science liaison teams, which are currently focused on gaining hospital formulary acceptance for SURFAXIN and adoption of AFECTAIR; (ii) investments in the technology transfer to a CMO of its manufacturing process for lyophilized KL4 surfactant and the optimization of its CAG device, both for use in the planned AEROSURF phase 2 clinical program; and (iii) a one-time \$2.0 million charge associated with certain contractual severance obligations related to the resignation of its former Chief Executive Officer, including \$0.8 million of non-cash stock-based compensation charges.

Operating cash outflows for the quarter ended December 31, 2012 were \$9.2 million. For the first quarter of 2013, the Company anticipates operating cash outflows of approximately \$10.5 million, before taking into account financing activities.

As of December 31, 2012, the Company had cash and cash equivalents of \$26.9 million. In February 2013, the Company secured access to up to \$55 million in potential additional financing through a \$30 million secured loan facility with Deerfield (Deerfield Facility) and a \$25 million ATM Program with Stifel. Under terms of the Deerfield Facility, Deerfield advanced to the Company \$10 million upon execution of the agreement and agreed to advance an additional \$20 million upon the first commercial sale of SURFAXIN. Amounts outstanding under the Deerfield Facility accrue interest at 8.75% and principal repayments are payable on the fourth, fifth and sixth anniversary of the agreement except that, if certain revenue or market capitalization milestones are achieved, the fourth and fifth anniversary payments may be deferred for one year. In conjunction with the \$10 million advance, Deerfield received warrants to purchase approximately 2.3 million shares of common stock at an exercise price of \$2.81. Upon disbursement of the \$20 million advance, Deerfield will receive additional warrants to purchase approximately 4.7 million shares of common stock at an exercise price of \$2.81. All of the warrants will expire on the sixth anniversary date of the Deerfield Facility. Under the ATM Program, the Company may sell, at such times and amounts as it deems appropriate, up to \$25 million of shares of common stock to support its business plans. The Company is not required to sell any shares at any time during the term of the ATM Program.

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The Company had 43.7 million and 24.6 million shares of common stock outstanding as of December 31, 2012 and 2011, respectively.

As of December 31, 2012, the Company reported a common stock warrant liability of \$6.3 million, of which \$6.2 million is related to five-year warrants issued in February 2011. These warrants state that there is no circumstance in which the Company shall be required to effect a net 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.

Readers are referred to, and encouraged to read in their entirety, the Forms 8-K regarding the matters referred to herein, including any exhibits attached thereto, and the Company's Annual Report on Form 10-K for the year ended December 31, 2012 to be 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 today at 10:00 AM ET to discuss the foregoing. The call in number is (877) 215-0093. The international call in number is (706) 679-3237. The passcode is 20394319. This audio webcast will be available at [http://us.meeting-stream.com/discoverylaboratories\\_031313](http://us.meeting-stream.com/discoverylaboratories_031313) and [www.discoverylabs.com](http://www.discoverylabs.com). The replay number to hear the conference call is (855) 859-2056 or (404) 537-3406 using the same conference call password listed above.

#### **About Discovery Labs**

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to advance a new standard in respiratory critical care. Discovery Labs' novel proprietary KL4 surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant. Discovery Labs is also developing its proprietary drug delivery technologies to enable efficient delivery of aerosolized KL4 surfactant and other inhaled therapies.

Discovery Labs' strategy is initially focused on the development of its technologies to improve the management of respiratory distress syndrome (RDS) in premature infants. SURFAXIN is the first synthetic, peptide-containing (KL4) surfactant approved by the FDA and the only alternative to animal-derived surfactants. AEROSURF is a drug/device combination product being developed to enable efficient delivery of aerosolized KL4 surfactant. If approved, AEROSURF potentially will provide neonatologists with the ability to deliver surfactant therapy using a less-invasive method and thereby enable the treatment of premature infants who could benefit from surfactant therapy but who are currently not treated. Discovery Labs believes that its RDS product portfolio has the potential to become the new standard of care for RDS and, over time, significantly expand the current worldwide RDS market.

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

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**About SURFAXIN**

SURFAXIN (lucinactant) intratracheal suspension 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)

**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 and expected results, to differ materially from the statements made. Examples of such risks and uncertainties include risks that: in addition to revenues from the sale of its commercial products, Discovery Labs will require significant additional capital to sustain its operations and development activities, including planned clinical programs; Discovery Labs may not meet the conditions for the \$20 million disbursement under the Deerfield Facility, or be unable to access its ATM Program or committed equity financing facility (CEFF), or additional financings could result in substantial equity dilution, or may be unable to secure additional capital when needed, from strategic alliances; Discovery Labs may experience a significant delay beyond the second quarter of 2013 in the commercial introduction of SURFAXIN and AFECTAIR in the United States, or may not achieve the level of expected revenue; that Discovery Labs may be unable to identify potential strategic partners or collaborators or enter into strategic transactions to develop and commercialize its products, if approved, in a timely manner, if at all; Discovery Labs may be unable to manage its growth effectively and timely modify its business strategy as needed to respond to developments in its commercial operations, development activities, business and other factors; Discovery Labs' sales and marketing organization may be unable to effectively market SURFAXIN and AFECTAIR in the U.S. in a timely manner, if at all, and may not succeed in developing market awareness of its products or its product candidates will not gain market acceptance by physicians, patients, healthcare payers and others in the medical community; that Discovery Labs will not meet the rigorous regulatory requirements required for approval of any drug, drug-device combination or medical device products that Discovery Labs may develop, including that: (a) Discovery Labs and the U.S. Food and Drug Administration (FDA) or other regulatory authorities will not be able to agree on the matters raised during regulatory reviews, or Discovery Labs may be required to conduct significant additional activities to potentially gain approval of its product candidates, if ever, (b) the FDA or other regulatory authorities may not accept or may withhold or delay consideration of any of Discovery Labs' applications, or may not approve or may limit approval of Discovery Labs' products to particular indications or impose unanticipated label limitations, and (c) changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval; Discovery Labs may be unable to develop and manufacture drug products, AFECTAIR<sup>®</sup> aerosol-conducting airway connectors and capillary aerosol generator (CAG) devices for clinical studies, and, if approved, for commercialization of drug and combination drug-device products and, if cleared for marketing, medical device products, including risks of technology transfers to contract manufacturers and problems or delays encountered by Discovery Labs, its contract manufacturers or suppliers in manufacturing drug products, drug substances and other materials and aerosol-conducting airway connectors and CAG devices on a timely basis or in an amount sufficient to support Discovery Labs' development efforts and, if approved, commercialization; Discovery Labs research and development activities may involve (i) time-consuming and expensive pre-clinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or fail, and (ii) the need for sophisticated and extensive analytical methodologies; Discovery Labs or its strategic partners or collaborators will not be able to retain, or attract, qualified personnel; Discovery Labs may be unable to maintain compliance with The Nasdaq Capital Market listing requirements; Discovery Labs may be unable to maintain and protect the patents and licenses related to its products, or other companies may develop competing therapies and/or technologies, or health care reform may adversely affect Discovery Labs; Discovery Labs may be involved in legal proceedings, including securities actions and product liability claims; and health care reform may adversely affect Discovery Labs. These and other risks and uncertainties are 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:****Investor Relations:**

Michael Rice, LifeSci Advisors - 646.597.6979

John Tattory, Vice President of Finance, Discovery Labs – 215.488.9418

**Media Relations:**

Michael Parks, Pitch360 - 484.356.7105 or [Michael@pitch360inc.com](mailto:Michael@pitch360inc.com)

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**Condensed Consolidated Statement of Operations**  
(in thousands, except per share data)

	Three Months Ended December 31, (unaudited)		Twelve Months Ended December 31 (unaudited)	
	2012	2011	2012	2011
Revenue from collaborative arrangement and grants	\$ 195	\$ –	\$ 195	\$ 582
Operating expenses: <sup>(1)</sup>				
Research and development	6,088	4,014	21,570	17,230
Selling, general and administrative	6,532	1,889	16,444	7,864
Total expenses	<u>12,620</u>	<u>5,903</u>	<u>38,014</u>	<u>25,094</u>
Operating loss	(12,425)	(5,903)	(37,819)	(24,512)
Change in fair value of common stock warrant liability <sup>(1)</sup>	5,618	1,603	555	3,560
Other income / (expense), net	(8)	(1)	(51)	(13)
Net loss	<u>\$ (6,815)</u>	<u>\$ (4,301)</u>	<u>\$ (37,315)</u>	<u>\$ (20,965)</u>
Net loss per common share	<u>\$ (0.16)</u>	<u>\$ (0.18)</u>	<u>\$ (0.95)</u>	<u>\$ (0.93)</u>
Weighted avg. common shares outstanding	43,521	24,309	39,396	22,660

(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 and twelve months ended December 31, 2012, the charges for depreciation and stock-based compensation were \$1.1 million (\$0.1 million in R&D and \$1.0 million in S,G&A) and \$2.4 million (\$0.5 million in R&D and \$1.9 million in S,G&A), respectively. Included in non-cash charges for the three and twelve months ended December 31, 2012 are one-time charges of \$0.8 million associated with stock based compensation modification charges related to the severance agreement with its former CEO. For the three and twelve months ended December 31, 2011, the charges for depreciation and stock-based compensation were \$0.4 million (\$0.1 million in R&D and \$0.3 million in S,G&A) and \$0.9 million (\$0.3 million in R&D and \$0.6 million in S,G&A), respectively.

**Condensed Consolidated Balance Sheets**  
(in thousands)

	December 31, 2012 (Unaudited)	December 31, 2011
<b><u>ASSETS</u></b>		
Current Assets:		
Cash and cash equivalents	\$ 26,892	\$ 10,189
Prepaid expenses and other current assets	914	442
Total current assets	<u>27,806</u>	<u>10,631</u>
Property and equipment, net	1,737	2,293
Other assets	400	400
Total Assets	<u>\$ 29,943</u>	<u>\$ 13,324</u>
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current Liabilities:		
Accounts payable	\$ 1,166	\$ 1,111
Accrued expenses	4,159	2,972
Common stock warrant liability	6,305	6,996
Equipment loan and capitalized leases, current portion	69	68
Total Current Liabilities	<u>11,699</u>	<u>11,147</u>
Long-Term Liabilities:		
Equipment loan and capitalized leases, non-current portion & other liabilities	591	913
Total Liabilities	<u>12,290</u>	<u>12,060</u>
Stockholders' Equity	17,653	1,264
Total Liabilities and Stockholders' Equity	<u>\$ 29,943</u>	<u>\$ 13,324</u>