
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 8, 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 August 8, 2013, Discovery Laboratories, Inc. (the "Company") issued a press release highlighting the results of operations for the year and quarter ended June 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 June 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.

The Press Release provides certain program updates relating to the Company's SURFAXIN® and AEROSURF® programs. In addition, for the third quarter of 2013, the Company anticipates net cash outflows of approximately \$10.5 million, before taking into account a potential debt facility advance or financing activities.

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 August 8, 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.

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 8, 2013



Discovery Labs Reports Second Quarter 2013 Financial Results

WARRINGTON, PA — August 8, 2013 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today reported financial results for the second quarter ended June 30, 2013 and also provided a business update. The Company will host a conference call this morning at 10:00 AM ET. Conference call details are below.

Key updates include:

- **SURFAXIN®**: On June 7, 2013, the Company submitted a response to a request by the U.S. Food and Drug Administration (FDA) for more information related to the Company's recently updated product specifications for SURFAXIN. The Company expects that the FDA may take up to four months from the date of its submission to review the information provided. If the FDA agrees with the response, the Company expects to proceed with the commercial introduction of SURFAXIN in the fourth quarter of 2013. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA for use in neonatal medicine and is the only approved alternative to animal-derived surfactants in the U.S., which are currently the standard of care for respiratory distress syndrome (RDS).
- **AEROSURF®**: AEROSURF is a novel combination drug-device product being developed to deliver the Company's synthetic, peptide-containing surfactant in aerosolized form using its proprietary aerosolization technologies. AEROSURF could potentially allow for the administration of the Company's surfactant to premature infants without having to use invasive endotracheal intubation and may enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy and currently are not treated. The Company's AEROSURF development plan remains on track for the initiation of the phase 2 clinical program in the fourth quarter of 2013.
- **Financial results**: For the second quarter of 2013, the Company reported an operating loss of \$10.8 million with net cash outflows before financings of \$10.2 million.

"We believe our technology platform forms the basis to develop products that have the potential to become the new standard of care for RDS. Success with our near-term SURFAXIN and AEROSURF milestones will represent significant progress towards achieving this goal," commented John G. Cooper, President and Chief Executive Officer at Discovery Labs. "Our commercial and medical affairs organizations are actively building relationships with the neonatal medical community in preparation for the planned commercial introduction of SURFAXIN. For AEROSURF, we are working with nationally recognized neonatologists who represent leading neonatal medical centers and who, as members of our steering committee, are playing an active role in guiding the design of the AEROSURF clinical program."

Summary Financial Results for the Second Quarter Ended June 30, 2013

For the quarter ended June 30, 2013, the Company reported a net loss of \$8.6 million (\$0.18 basic net loss per share) on 49.1 million weighted-average common shares outstanding, compared to a net loss of \$7.1 million (\$0.16 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 non-cash income of \$2.5 million and \$1.7 million in 2013 and 2012, respectively.

The Company reported an operating loss of \$10.8 million for the quarter ended June 30, 2013 compared to an operating loss of \$8.8 million for the same period in 2012. Net cash outflows before financing activities for the quarter ended June 30, 2013 were \$10.2 million compared to \$8.8 million for the same period in 2012. The increase in operating loss from 2012 to 2013 is due primarily to (i) an increase of \$1.2 million in investment in the Company's own specialty commercial and medical affairs organizations specializing in neonatal/pediatric respiratory critical care in NICUs/PICUs across the U.S.; and, (ii) an increase of \$1.7 million in investment in the AEROSURF development program, primarily to prepare our proprietary capillary aerosol generator for clinical use in anticipation of our AEROSURF phase 2 clinical trials, and advance the technology transfer of our lyophilized KL4 surfactant manufacturing process to a leading contract manufacturing organization with expertise in lyophilization.

On May 15, 2013, the Company completed a public offering of 9.5 million shares of common stock, at a price of \$1.50 per share resulting in net proceeds to the Company (after underwriter fees and anticipated expenses) of approximately \$13.2 million. The Company also granted the underwriter a 30-day option to purchase up to an additional 1.425 million shares of common stock at an offering price of \$1.50. On May 31, 2013, the underwriter exercised its option and purchased 1.347 million additional shares that resulted in net proceeds to the Company (after underwriter fees) of approximately \$1.9 million. The total net proceeds to the Company from the public offering were approximately \$15.1 million.

As of June 30, 2013, the Company had cash and cash equivalents of \$31.3 million. Additionally, the Company potentially may receive \$20 million under a \$30 million loan facility with affiliates of Deerfield Management Company, L.P. if the first commercial sale of SURFAXIN occurs on or before December 31, 2013. The initial \$10 million was advanced upon execution of the agreement in February 2013. Also, the Company has access to up to \$25 million under its ATM Program with Stifel, Nicolaus & Company, Incorporated. Under the ATM Program, the Company may, at its discretion and subject to certain limitations, raise additional capital to support its business plans. The Company has not used the ATM Program in 2013.

As of June 30, 2013, the Company had approximately \$7 million of accounts payable and accrued expenses and \$10 million of debt under the Deerfield Facility, which has been reported as long-term debt, net of \$3.8 million of discounts. Additionally, the Company reported a common stock warrant liability of \$3.6 million, predominantly related to five-year warrants issued in February 2011. These warrants are not subject to cash settlement; however, they are 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 54.8 and 43.7 million shares of common stock outstanding as of June 30, 2013 and December 31, 2012, respectively.

Readers are referred to, and encouraged to read in their entirety the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 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 20041973. This audio webcast will be available at http://us.meeting-stream.com/discoverylaboratories_080813 and 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 focused on advancing 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 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, significantly expand the current worldwide RDS market.

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, and may be unable in a timely manner, if at all, to identify potential strategic partners to support product development and, if approved, to commercialize products in markets outside the U.S.; or to access its Deerfield Facility or other debt or equity financings, which, if available, could result in substantial equity dilution; risks related to the delay in commercial availability of SURFAXIN, including that (a) Discovery Labs' plan to maintain its commercial and medical affairs capabilities and continue its investments in the AEROSURF program limits its ability to reduce cash outflows, (b) the FDA may not review the recently submitted response within four months or may not agree with the response, which could further delay or prevent the commercial introduction of SURFAXIN, and (c) Discovery Labs may lose access to \$20 million under the Deerfield Facility if the delay extends beyond December 31, 2013; 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 time-consuming and expensive pre-clinical studies and clinical trials, which may be subject to potentially significant delays or regulatory holds, or fail, and the need for sophisticated and extensive analytical methodologies; 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, (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:**Company**

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

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

Includes non-cash charges for depreciation and stock-based compensation the three months ended June 30, 2013 and 2012 of \$0.8 million (\$0.4 million in R&D and \$0.4 million in SG&A) and \$0.7 million (\$0.4 million in R&D and \$0.3 million in SG&A), respectively; and for the six months ended June 30, 2013 and 2012, \$1.3 million (\$0.7 million in R&D and \$0.6 million in SG&A) and \$1.4 million (\$0.8 million in R&D and \$0.6 million in SG&A), respectively.

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

	June 30,	December 31,
	2013	2012
	(Unaudited)	
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 31,253	\$ 26,892
Inventory	36	195
Prepaid expenses and other current assets	618	719
Total current assets	31,907	27,806
Property and equipment, net	1,493	1,737
Restricted cash and other assets	507	400
Total Assets	\$ 33,907	\$ 29,943
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,919	\$ 1,166
Accrued expenses	4,739	4,159
Common stock warrant liability	3,619	6,305
Equipment loan and capitalized leases, current portion	71	69
Total Current Liabilities	10,348	11,699
Long-Term Liabilities:		
Long-term debt, net of discount of \$3.8 million at June 30, 2013 and \$0 at December 31, 2012, respectively	6,201	–
Equipment loan, non-current portion & other liabilities	542	591
Total Liabilities	17,091	12,290
Stockholders' Equity:	16,816	17,653
Total Liabilities and Stockholders' Equity	\$ 33,907	\$ 29,943