

**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**

**August 3, 2011**

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 3, 2011, Discovery Laboratories, Inc. (the “Company”) issued a press release highlighting the results of operations for the quarter ended June 30, 2011, and providing an update on certain business matters. 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 March 31, 2011 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 August 3, 2011, the Company issued a press release highlighting the results of operations for the quarter ended June 30, 2011, and providing an update on its lead pipeline programs. For the second half of 2011, the Company anticipates net cash outflows of approximately \$12 million, before taking into account any potential financing activities.

Subject to the note relating to the press release in Item 2.02 to 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 3, 2011

**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 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.

**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/ W. Thomas Amick  
Name: W. Thomas Amick  
Title: Chairman of the Board and Chief Executive Officer

Date: August 3, 2011



**Discovery Labs Reports Second Quarter Financial Results and  
Provides an Update on Lead Pipeline Programs**

**Warrington, PA — August 3, 2011 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**, a specialty biotechnology company dedicated to improving the standard of respiratory critical care through its KL<sub>4</sub> surfactant and aerosol drug delivery technologies, today reports financial results for the second quarter ended June 30, 2011 and provides an update on lead pipeline programs. The Company will host a conference call this morning at 10:00 AM EDT. Conference call details are below.

Selected highlights, discussed in greater detail below, include:

- **SURFAXIN®** – The Company remains on track to file the Complete Response with the U.S. Food and Drug Administration (“FDA”) in the third quarter 2011, potentially leading to the approval of SURFAXIN for the prevention of respiratory distress syndrome (RDS) in premature infants in the first quarter of 2012.
- **AFECTAIR™** – AFECTAIR is a proprietary disposable patient interface technology that resulted from ongoing efforts to advance the AEROSURE® program. The Company recently announced its intention to seek market authorization for its initial AFECTAIR product in the U.S. in the fourth quarter of 2011, and in the European Union (EU) in the first half of 2012.
- For the second quarter ended June 30, 2011, the Company reported a net operating loss of \$6.4 million and net cash outflows of \$6.1 million. As of June 30, 2011 the Company had cash and cash equivalents of \$21.5 million. The Company also has its 2010 Committed Equity Financing Facility that, subject to certain conditions, may allow it in the future to raise additional capital to support its business plans. Additionally, if the market price of the Company’s common stock should exceed \$2.94 at any time prior to May 2012, the Company could potentially realize up to an additional \$14.7 million from the potential exercise of fifteen-month warrants that it issued in February 2011.

“We have made great progress on a number of key development initiatives that we believe fundamentally strengthen our Company’s pipeline.” said W. Thomas Amick, Chairman of the Board and Chief Executive Officer, Discovery Labs. “With both AFECTAIR and SURFAXIN potentially arriving on the market in 2012, we are making great progress toward our goal of improving the standard of respiratory critical care.”

**Selected Pipeline Updates:**

- **SURFAXIN (lucinactant) for the prevention of RDS in premature infants:** The Company has conducted a comprehensive preclinical program with a view to satisfying the FDA as to the final validation of its fetal rabbit biological activity test (BAT), which is a key remaining issue that must be addressed to potentially gain FDA marketing approval for SURFAXIN in the U.S. The Company has had several interactions with the FDA in an effort to ensure that the comprehensive preclinical program will ultimately satisfy the FDA. The Company has successfully completed the manufacture of a sufficient number of SURFAXIN batches to generate the additional data requested by the FDA, and expects to complete all related analytical and concordance testing in August 2011. The Company believes it remains on track to file a Complete Response in the third quarter of 2011, which, after an anticipated six-month FDA review period, could lead to the potential approval of SURFAXIN in the first quarter of 2012.
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- **SURFAXIN LS™ (lyophilized lucinactant) for neonatal RDS:** SURFAXIN LS is an important life-cycle development program intended to further improve upon the SURFAXIN product profile and potentially provide access to international markets. The Company continues its efforts to advance this program and plans to seek regulatory guidance from the FDA and the European Medicines Agency (EMA) regarding the development program. The Company expects to engage in discussions with the FDA in the second half of 2011.
- **Aerosolized Drug Delivery Technology:** AFECTAIR was developed as an important component of the AEROSURF development program and is a proprietary, disposable patient interface adapter that simplifies the delivery of aerosolized medications to critical-care patients requiring ventilatory support. Based on an assessment conducted by an independent market research firm, the Company believes that the AFECTAIR product series could represent a revenue opportunity of approximately \$50 million to \$75 million at peak annual sales in the U.S. and EU combined. The Company plans to seek market authorization for the initial AFECTAIR product in the U.S. in the fourth quarter of 2011, and in the EU in the first half of 2012. If market authorization is obtained, the Company believes that it may be in a position to introduce the initial AFECTAIR product in both markets in 2012. AFECTAIR product performance data have been accepted for presentation at the November 2011 American Association of Respiratory Care conference.

### **Summary Financial Position and Results for the Quarter ended June 30, 2011**

For the quarter ended June 30, 2011, the Company reported a net loss of \$8.1 million (\$0.34 per share) on 24.0 million weighted-average common shares outstanding, compared to a net loss of \$0.8 million (\$0.07 per share) on 10.7 million weighted-average common shares outstanding for the same period in 2010. 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 expense of \$1.7 million for the quarter ended June 30, 2011 and non-cash income of \$5.5 million for the quarter ended June 30, 2010.

The Company reported an operating loss of \$6.4 million for the quarter ended June 30, 2011 compared with \$6.2 million for the quarter ended June 30, 2010. Excluding non-cash items related to depreciation and stock-based compensation, the operating loss was \$5.9 million for the quarter ended June 30, 2011, compared with \$5.5 million for the quarter ended June 30, 2010. The increase in the operating loss in 2011 is principally due to activities related to the filing of the SURFAXIN Complete Response and the comprehensive assessment of the operational, regulatory and commercial requirements for AFECTAIR, offset by \$0.2 million of revenue recognized in 2011 under our grant from the National Institutes of Health (NIH) to support the development of the Company's program for aerosolized KL<sub>4</sub> surfactant for RDS.

As of June 30, 2011 the Company had cash and cash equivalents of \$21.5 million. Additionally, the Company currently has its 2010 Committed Equity Financing Facility (CEFF) that, subject to certain conditions, including price and volume limitations, may allow the Company in the future to raise additional capital to support its business plans. Under the CEFF (which expires in June 2013), there are 1.3 million shares available for potential future issuance. Additionally, in connection with a public offering conducted in February 2011, the Company issued fifteen-month warrants (expiring May 2012) to purchase 5.0 million shares of common stock at an exercise price of \$2.94. If the market price of the Company's common stock should exceed \$2.94 at any time prior to May 2012, the Company may realize up to an additional \$14.7 million in proceeds from the potential exercise of the fifteen month warrants.

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Net cash outflows for the second quarter of 2011 were \$6.1 million. For the second half of 2011, the Company anticipates net cash outflows of approximately \$12 million, before taking into account any potential financing activities.

As of June 30, 2011, the Company reported a common stock warrant liability of \$10.0 million, as compared to \$8.3 million as of March 31, 2011. The increase of \$1.7 million represents the change in fair value of certain outstanding common stock warrants accounted for as derivative liabilities, due primarily to an increase in the price of the Company's common stock as of June 30, 2011 as compared to March 31, 2011. The balance of the common stock warrant liability predominantly relates to the issuance, in February 2011, of five-year warrants that qualify for liability accounting due to certain price-related, anti-dilution provisions. These warrants may be exercised for cash only and expressly state that there is no circumstance in which the Company shall be required to settle the warrants in cash; however, due to the nature of the anti-dilution provisions, to comply with applicable accounting guidelines (Accounting Standards Codification Topic 815), these warrants were classified as derivative liabilities and reported as of June 30, 2011 at an estimated fair value of \$8.7 million using a trinomial valuation model.

The Company had 24.2 million, 24.1 million and 13.8 million common shares outstanding as of June 30, 2011, March 31, 2011 and December 31, 2010, respectively.

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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 to be filed with the Securities and Exchange Commission, which includes further detail on above-referenced transactions and the Company's business plans and operations, financial condition and results of operations.

SURFAXIN, SURFAXIN LS, AEROSURF and the Company's other aerosolized KL<sub>4</sub> surfactant drug product candidates are investigational medications and are not approved by the FDA or any other world health regulatory authority for use in humans. AFECTAIR, the Company's proprietary patient interface adapter, is an investigational device and not approved by the FDA or any other world health regulatory authority for use in humans.

#### **Conference Call Details**

Discovery Labs will hold a conference call today at 10:00 AM EDT to further discuss the foregoing. The call in number is (866) 332-5218. The international call in number is (706) 679-3237. This audio webcast will be available through a live broadcast on the Internet at [http://us.meeting-stream.com/discoverylaboratories\\_080311](http://us.meeting-stream.com/discoverylaboratories_080311) and [www.discoverylabs.com](http://www.discoverylabs.com). The replay number to hear the conference call is (855) 859-2056 or (404) 537-3406. The passcode is 85213033.

#### **About Discovery Labs**

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to create life-saving products for patients with respiratory disease and improve the standard of care for pulmonary medicine. Discovery Labs' novel proprietary KL<sub>4</sub> surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, lyophilized and aerosol formulations. Discovery Labs is also developing its proprietary drug delivery technologies – capillary aerosol generator and novel patient interface adapters – to enable efficient, targeted upper respiratory or alveolar delivery of aerosolized KL<sub>4</sub> surfactant. Discovery Labs believes that its proprietary technology makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at [www.Discoverylabs.com](http://www.Discoverylabs.com).

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**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 to differ materially from the statements made. Examples of such risks and uncertainties are: risks relating to the rigorous regulatory requirements required for approval of any drug or drug-device combination 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; risks relating to Discovery Labs' research and development activities, including (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, including an acceptable biological activity test as well as other quality control release and stability tests to satisfy the requirements of the regulatory authorities; risks relating to Discovery Labs' ability to develop and manufacture drug products, and capillary aerosol generators and patient interface systems for clinical studies, and, if approved, for commercialization of drug and combination drug-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 capillary aerosol generators and patient interface systems on a timely basis or in an amount sufficient to support Discovery Labs' development efforts and, if approved, commercialization; the risk that Discovery Labs may be unable to identify potential strategic partners or collaborators to develop and commercialize its products, if approved, in a timely manner, if at all; the risk that Discovery Labs will not be able in a changing financial market to raise additional capital or enter into strategic alliances or collaboration agreements, or that the ongoing credit crisis will adversely affect the ability of Discovery Labs to fund its activities, or that additional financings could result in substantial equity dilution; the risk that Discovery Labs will not be able to access credit from its committed equity financing facility (CEFF), or that the minimum share price at which Discovery Labs may access the CEFF from time to time will prevent Discovery Labs from accessing the full dollar amount potentially available under the CEFF; the risk that Discovery Labs or its strategic partners or collaborators will not be able to retain, or attract, qualified personnel; the risk that Discovery Labs will be unable to maintain compliance with The Nasdaq Capital Market listing requirements, which could cause the price of Discovery Labs' common stock to decline; the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten Discovery Labs' ability to continue as a going concern; the risks that 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; risks of legal proceedings, including securities actions and product liability claims; risks relating to 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 G. Cooper, President and Chief Financial Officer  
215-488-9490

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

	Three Months Ended June 30, (unaudited)		Six Months Ended June 30 (unaudited)	
	2011	2010	2011	2010
Revenue from collaborative arrangement and grants	\$ 201	\$ -	\$ 582	\$ -
Operating expenses: <sup>(1)</sup>				
Research and development	4,615	4,363	9,235	8,496
General and administrative	1,966	1,865	3,786	4,797
Total expenses	<u>6,581</u>	<u>6,228</u>	<u>13,021</u>	<u>13,293</u>
Operating loss	(6,380)	(6,228)	(12,439)	(13,293)
Change in fair value of common stock warrant liability <sup>(1)</sup>	(1,693)	5,519	535	6,749
Other income / (expense), net	(3)	(84)	(9)	(307)
Net loss	<u>\$ (8,076)</u>	<u>\$ (793)</u>	<u>\$ (11,913)</u>	<u>\$ (6,851)</u>
Net loss per common share	\$ (0.34)	\$ (0.07)	\$ (0.56)	\$ (0.69)
Weighted avg. common shares outstanding	24,027	10,695	21,086	9,942

(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 six months ended June 30, 2011, the charges for depreciation and stock-based compensation were \$0.5 million (\$0.4 million in R&D and \$0.1 million in G&A) and \$1.0 million (\$0.7 million in R&D and \$0.3 million in G&A), respectively. For the three and six months ended June 30, 2010, the charges for depreciation and stock-based compensation were \$0.7 million (\$0.4 million in R&D and \$0.3 million in G&A) and \$1.5 million (\$0.9 million in R&D and \$0.6 million in G&A), respectively.

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

	June 30, 2011 (Unaudited)	December 31, 2010
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 21,542	\$ 10,211
Prepaid expenses and other current assets	299	285
Total current assets	<u>21,841</u>	<u>10,496</u>
Property and equipment, net	2,839	3,467
Other assets	568	574
Total Assets	<u>\$ 25,248</u>	<u>\$ 14,537</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 1,986	\$ 1,685
Accrued expenses	2,973	3,286
Common stock warrant liability	10,021	2,469
Equipment loan and capitalized leases, current portion	93	136
Total Current Liabilities	<u>15,073</u>	<u>7,576</u>
Long-Term Liabilities:		
Equipment loan and capitalized leases, non-current portion & other liabilities	968	935
Total Liabilities	<u>16,041</u>	<u>8,511</u>
Stockholders' Equity	9,207	6,026
Total Liabilities and Stockholders' Equity	<u>\$ 25,248</u>	<u>\$ 14,537</u>