

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 6, 2008

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 6, 2008, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended June 30, 2008. 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 attached hereto 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 6, 2008, Discovery Laboratories, Inc. (the “Company”) held a conference call to discuss the financial results for the second quarter ended June 30, 2008. On the call, the Company provided an estimate of the anticipated net cash outflows for the third quarter of 2008 of approximately \$7.0 million which includes \$2.5 million received from Chrysalis Technologies (Chrysalis, a division of Philip Morris USA, Inc.) in accordance with a modified collaboration agreement dated May 22, 2007.

On August 6, 2008, the Company issued a press release announcing progress in addressing key remaining items identified in the May 1, 2008 Approvable Letter received by the Company from the FDA in connection with its New Drug Application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The press release, dated August 6, 2008, is filed as Exhibit 99.2 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated August 6, 2008

99.2 Press release dated August 6, 2008

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.

Date: August 7, 2008

By: /s/ Robert J. Capetola

Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer



Discovery Labs Reports Second Quarter 2008 Financial Results

Warrington, PA — August 6, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced financial results for the second quarter ended June 30, 2008. The Company will host a conference call today at 10:00 AM EDT. **The call-in number is 866-332-5218.**

For the quarter ended June 30, 2008, the Company reported a net loss of \$10.2 million (or \$0.11 per share) on 96.7 million weighted average common shares outstanding compared to a net loss of \$10.4 million (or \$0.12 per share) on 83.8 million weighted average common shares outstanding for the same period in 2007. For the six months ended June 30, 2008, the Company reported a net loss of \$19.9 million (or \$0.21 per share) on 96.7 million weighted average common shares outstanding compared to a net loss of \$18.7 million (or \$0.24 per share) on 76.9 million weighted average common shares outstanding for the same period in 2007. As of June 30, 2008, the Company had 96.8 million common shares outstanding.

As of June 30, 2008, the Company had cash and marketable securities of \$33.4 million. In the second quarter 2008, cash burn from operating activities, capital expenditures and debt service was \$8.2 million. The Company also has access to two Committed Equity Financing Facilities (CEFF). The CEFF allows the Company, at its discretion, to raise capital (subject to certain conditions, including price and volume limitations) to support its business plans. As of June 30, 2008, under the 2008 CEFF, approximately 19.3 million shares were available for issuance for future financings (not to exceed an aggregate of \$60.0 million) and, under the 2006 CEFF, approximately 5.2 million shares were available for issuance for future financings (not to exceed an aggregate of \$35.5 million). The 2008 CEFF expires in June 2011 and the 2006 CEFF expires in April 2009. Under the terms of the CEFF, the Company determines the exact timing and amount of any CEFF financings, subject to certain conditions.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, "The Company is focused on gaining FDA approval of Surfaxin by providing the FDA with the additional information outlined in the May 1 Approvable Letter and clarified in our June 18 meeting. Current assessment of our timelines and plans continues to support the submission of our Complete Response to the Approvable Letter and, assuming a Class 1 review period, potential FDA approval for Surfaxin in 2008. While we work to achieve this milestone, we are diligently managing our financial resources, planning a cash burn from operations, capital expenditures and debt service of \$7.0 million for the third quarter, and have already offset a significant portion of this burn with the judicious use of the CEFF."

Second Quarter 2008 Financial Results:

The net loss for the quarter ended June 30, 2008 was \$10.2 million compared to \$10.4 million for the same period in 2007. Included in the second quarter 2008 and 2007 net loss is a charge of \$1.2 million and \$1.7 million, respectively, associated with stock-based compensation expense per Financial Accounting Standards No. 123R (FAS 123(R)).

The primary components of the second quarter 2008 results included:

- \$2.5 million of revenue associated with completion of the technology transfer of the capillary aerosolization technology in accordance with the modified license agreement with Chrysalis. Payment of this \$2.5 million is expected in the third quarter of 2008. Under the modified agreement, Chrysalis agreed to pay \$4.5 million to the Company to support further development of the capillary aerosolization technology. In the second quarter of 2008, the Company received \$2.0 million associated with the execution of the modified agreement in the first quarter of 2008.
- research and development expenses of \$7.4 million associated with (a) manufacturing development and quality assurance and analytical activities to support the production of clinical and potential commercial drug requirements for Surfaxin and the Company's Surfactant Replacement Therapy (SRT) pipeline, (b) development of the Company's capillary aerosolization technology for the delivery of aerosolized SRT, (c) development of new formulations of the Company's surfactant technology, (d) internal research and development capabilities (scientific and clinical trial management, regulatory compliance, data management and biostatistics), (e) medical affairs (including medical science liaisons) to provide scientific and medical education support for Surfaxin and the Company's SRT pipeline, and (f) direct expenses to advance the Company's SRT pipeline, including the Aerosurf program and the Phase 2 clinical trial using Surfaxin in children up to the age of two with Acute Respiratory Failure (ARF).
- general and administrative expenses of \$5.1 million, including \$1.8 million of pre-launch commercialization activities, related to the establishment of the Company's own U.S. commercial operations, in anticipation of the approval of Surfaxin. In addition, \$0.8 million is included in general and administrative expenses, associated with stock-based compensation per FAS123(R).

As of June 30, 2008, the Company had \$9.9 million outstanding under its long-term loan with PharmaBio Development Inc. d/b/a Novaquest (a strategic investment group of Quintiles Transnational Corp.). The outstanding principal, together with all accrued and unpaid interest is due and payable on April 30, 2010.

The Company has a secured credit facility with GE Business Financial Services Inc. (GE) to finance capital expenditures. Effective May 30, 2008, the facility was amended to extend the term an additional six months through November 30, 2008 to provide support for the Company's anticipated capital investments for the remainder of 2008. As of June 30, 2008, \$4.4 million was outstanding under this facility (\$2.9 million is classified as a current liability and \$1.5 million is classified as a long-term liability) and \$300,000 remained available.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' technology produces a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant. Discovery Labs believes that, with its proprietary technology, SRT has the potential, for the first time, to address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

SURFAXIN[®], the Company's lead product from its SRT pipeline, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. SURFAXIN is also being developed for other neonatal and pediatric indications. AEROSURF[™], Discovery Labs' aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at www.Discoverylabs.com.

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, including, without limitation, the risks that: Discovery Labs may be unable to respond, if at all, to the recent approvable letter for Surfaxin within the anticipated timeline and the response, when filed, may not satisfy the FDA; the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that Discovery Labs may file for its products, or may not approve any such applications or may limit marketing of such products to particular indications or impose unanticipated label limitations; changes in the national or international political and regulatory environment may make it more difficult for Discovery Labs to gain FDA or other regulatory approval of its products; Discovery Labs may be unable to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT); Discovery Labs' lengthy and costly research and development programs, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any of its products, including Surfaxin, may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs or its contract manufacturers or materials suppliers may be unable to successfully manufacture adequate supplies of its drug product or drug substances when needed or in amounts sufficient to meet demand; Discovery Labs may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs' drug products with innovative aerosolization technologies; Discovery Labs may be unable to profitably develop and market its products; Discovery Labs may be unable to maintain and protect the patents and licenses related to its SRT; other companies may develop competing therapies and/or technologies or health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in securities, product liability and other litigation. The foregoing risks and others are further 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.

Company Contact:

Lisa Caperelli, Investor Relations
215-488-9413

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	(unaudited)		(unaudited)	
	2008	2007	2008	2007
Revenue	\$ 2,500	\$ -	\$ 4,550	\$ -
Operating expenses: ⁽¹⁾				
Research and development	7,439	6,794	14,670	12,216
General and administrative	5,076	3,465	9,582	6,219
Total expenses	12,515	10,259	24,252	18,435
Operating loss	(10,015)	(10,259)	(19,702)	(18,435)
Other income / (expense)	(200)	(125)	(227)	(259)
Net loss	\$ (10,215)	\$ (10,384)	\$ (19,929)	\$ (18,694)
Net loss per common share	\$ (0.11)	\$ (0.12)	\$ (0.21)	\$ (0.24)
Weighted average number of common shares outstanding	96,691	83,825	96,670	76,907

⁽¹⁾ Expenses include a charge for stock-based employee compensation in accordance with the provisions of FAS 123(R). For the three and six months ended June 30, 2008, the charges associated with FAS 123(R) were \$1.2 million (\$0.4 million in R&D and \$0.8 million in G&A) and \$2.2 million (\$0.7 million in R&D and \$1.5 million in G&A), respectively. For the three and six months ended June 30, 2007, the charges associated with FAS 123(R) were \$1.7 million (\$0.5 million in R&D and \$1.2 million in G&A) and \$2.4 million (\$0.8 million in R&D and \$1.6 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	June 30,	December 31,
	2008	2007
	(unaudited)	
ASSETS		
Current Assets:		
Cash and marketable securities	\$ 33,364	\$ 53,007
Receivables, prepaid expenses and other current assets	2,857	611
Total Current Assets	36,221	53,618
Property and equipment, net	6,616	7,069
Restricted Cash	600	600
Other assets	1,182	1,457
Total Assets	\$ 44,619	\$ 62,744
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 3,001	\$ 757
Accrued expenses	5,079	7,087
Equipment loan and other liabilities	2,875	2,625
Total Current Liabilities	10,955	10,469
Long-Term Liabilities:		
Loan payable, including accrued interest	9,903	9,633
Equipment loan and other liabilities	2,442	3,861
Total Liabilities	23,300	23,963
Stockholders' Equity	21,319	38,781
Total Liabilities and Stockholders' Equity	\$ 44,619	\$ 62,744



Discovery Labs Reports Progress in Responding to Surfaxin FDA Approvable Letter

Warrington, PA - August 6, 2008, -- Discovery Laboratories, Inc. (Nasdaq:DSCO) announces that it has made significant progress in addressing key remaining requirements identified by the U.S. Food and Drug Administration (FDA) to gain marketing approval of Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Over the upcoming weeks, Discovery Labs will continue to conduct and finalize activities necessary to submit a Complete Response to the May 1, 2008 FDA Approvable Letter. Discovery Labs anticipates submitting a Complete Response in September 2008 and believes the response may be designated by the FDA as a Class 1 resubmission with a target review period of 60 days.

The May 1, 2008 Approvable Letter did not require any additional clinical trials to gain Surfaxin approval. Prior to receiving that Approvable Letter, Discovery Labs and the FDA had agreed to a proposed Surfaxin package insert setting forth prescribing information. Also, the FDA had successfully conducted a pre-approval inspection (PAI) of Discovery Labs' manufacturing operations. On June 18, 2008, Discovery Labs met with the FDA to clarify and reach agreement on addressing the key remaining requirements necessary to gain Surfaxin approval. These key requirements are:

Surfaxin Biological Activity Test

Based on discussions with the FDA several years ago, Discovery Labs qualified and validated a biological activity test in accordance with current Good Manufacturing Practices (cGMP) and successfully implemented this test for Surfaxin release and stability testing. In addition, as agreed to at a December 2006 Clarification Meeting with the FDA, Discovery Labs generated data in a well-characterized RDS animal model at a Surfaxin dose of 5.8 mL/kg (the 2007 Preclinical Study), which is the same dose that was used in the Phase 3 clinical studies of Surfaxin.

The 2007 Preclinical Study results, together with data generated from the biological activity test described above, support the comparability of Surfaxin drug product used in Discovery Labs Phase 3 clinical studies to the commercial manufacturing process for Surfaxin. In addition, these data were intended to establish final acceptance criteria for the biological activity test. The data from the biological activity test and the 2007 Preclinical Study were provided to and reviewed by the FDA during the Surfaxin review cycle that concluded with the May 1, 2008 Approvable Letter.

At the June 18, 2008 meeting, the FDA requested and Discovery Labs agreed to augment the previously-generated data by conducting additional Surfaxin biological activity tests at a dose of 5.8 mL/kg, which is different than the dose of 8.0 mL/kg historically employed for Surfaxin release and stability testing. In addition, Discovery Labs is contemporaneously conducting a related preclinical study using the same RDS animal model and dose (5.8 mL/kg) as that used in the 2007 Preclinical Study.

The data generated from these additional studies will be used to determine the final acceptance criteria for the biological activity test and to further confirm the comparability of Surfaxin drug product used in Discovery Labs' Phase 3 clinical trials to the commercial manufacturing process for Surfaxin. These additional studies are ongoing and are being conducted at the same laboratories previously used by Discovery Labs. Although these activities must be successfully concluded, Discovery Labs believes that the preliminary results achieved to date are encouraging and are expected to support Surfaxin approval.

Specifications for Lipid-Related Impurities in Surfaxin Active Pharmaceutical Ingredients (APIs)

Surfaxin is comprised of four active pharmaceutical ingredients (APIs); a novel peptide, a fatty acid and two phospholipids. To gain final marketing authorization by the FDA, Discovery Labs must satisfy International Conference of Harmonization (ICH) guidelines for the proposed specifications for certain lipid-related impurities in the two phospholipids.

At the June 18 meeting with the FDA, Discovery Labs discussed its approach to justify the levels of certain of the lipid-related impurities given their presence in the human lung at levels equal to or greater than those that exist in Surfaxin. At that meeting, the FDA requested additional information about the levels of these lipid-related impurities specific to the neonatal lung. In addition to reviewing scientific literature to satisfy the requirement that lipid-related impurities in Surfaxin's two phospholipids meet ICH guidelines, Discovery Labs has consulted with lipid-experts and has been working closely with its phospholipid suppliers to reduce lipid-related impurity levels to the ICH threshold limit.

To date, notable progress has been made. Based on recent analyses, Discovery Labs believes that it can satisfy the FDA requirements by either accepting the ICH threshold limits for certain lipid-related impurities and/or working with its phospholipid suppliers to further reduce impurity levels to the ICH threshold limits. Discovery Labs and its phospholipid suppliers are focused on successfully completing this approach over the upcoming weeks and obtaining all information necessary to support a September submission of a Complete Response.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, "I am extremely pleased with the results achieved to date and am confident that the upcoming Complete Response will satisfy the remaining FDA requirements to gain Surfaxin approval. We are positioning Surfaxin, the first peptide-containing, synthetic surfactant, to be the highest quality surfactant replacement therapy available. The state-of-the-art advancements made to our manufacturing operations, quality systems, analytical methods, and regulatory capabilities should favorably impact Surfaxin's acceptance by the medical community and meaningfully support the advancement of Discovery Labs' surfactant-based development pipeline."

Discovery Labs believes that it will be in a position to complete the activities related to satisfying all remaining FDA requirements and submit a Complete Response to this Approvable Letter in the September 2008 timeframe. Based on its understanding of FDA guidelines, and in consultation with outside experts, Discovery Labs believes that the FDA may designate the Complete Response to this Approvable Letter as a Class 1 resubmission, which would result in a target review period of 60 days (whereas a Class 2 resubmission would result in a 6-month target review period). If Discovery Labs' understanding of the timeline is correct, the potential approval of Surfaxin is anticipated in 2008.

DISCLOSURE NOTICE: The information in this press release includes certain “forward-looking” statements relating to, among other things, the remaining steps necessary for FDA approval of Surfaxin for the prevention of RDS in premature infants and Discovery Labs’ plans and expected timing to respond to the May 1, 2008 Approvable Letter. Although Discovery Labs believes that it has made significant progress towards gaining approval of Surfaxin, gaining approval of Surfaxin involves ongoing activities, the final results of which could vary materially from Discovery Labs’ expectations and the results obtained to date. Discovery Labs currently believes that it will succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants within the timeline outlined above; however, these activities and the ultimate outcomes are subject to a variety of risks, including but not limited to risks that (i) even if Discovery Labs is able to generate the additional data requested by the FDA and file its Complete Response to the Approvable letter within the timeline indicated above, the FDA may not be satisfied with the new data and may require Discovery Labs to perform further studies or undertake other activities that are presently not contemplated by Discovery Labs, (ii) Discovery Labs may not succeed in adequately addressing other items identified in the Approvable Letter and be unable to gain approval of Surfaxin within the timeline indicated above, (iii) Discovery Labs, in the process of preparing its response to the Approvable Letter, may identify unforeseen problems that have not yet been discovered, and (iv) the FDA could impose additional requirements to gain approval of Surfaxin. Any failure to provide information requested by the FDA or to adequately address the items raised in the Approvable Letter in Discovery Labs’ formal response to the Approvable Letter could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially prevent the approval of Discovery Labs’ other products.

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