

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 2, 2007

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 2, 2007, Discovery Laboratories, Inc. (the "Company") issued a press release announcing financial results for the second quarter ended June 30, 2007, and providing selected updates on the Company's Surfaxin® (lucinaquant) replacement therapies pipeline development. 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 2, 2007, the Company held a conference call to discuss the financial results for the second quarter ended June 30, 2007. On the call, the Company provided an estimate of aggregate cash outflows from operating and investing activities for the third fiscal quarter of 2007 of approximately \$9.0 million.

On August 2, 2007, the Company issued a press release (attached hereto as Exhibit 99.2) providing updates on the Company's progress in addressing previously-announced manufacturing and process validation stability issues and the April 2006 Approvable Letter from the Food and Drug Administration (FDA). Results from the three new Surfaxin process validation batches, which were manufactured consistent with guidance obtained from the FDA at a December 2006 meeting, indicate that the batches demonstrated acceptable stability through three months under the Company's comprehensive testing protocol. The process validation batches must demonstrate stability through six-months before the Company can file its formal response to the Approvable Letter.

The Company believes that it has made significant progress in addressing the outstanding issues identified in the Approvable Letter, which focused on the Chemistry, Manufacturing and Controls (CMC) section of the New Drug Application (NDA) for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The Company is currently focused on completing the experiments, and compiling and analyzing the data for submission to the FDA, and believes that it remains on track to file its formal response in the October 2007 timeframe, followed by an anticipated six-month review cycle by the FDA for potential approval of the Surfaxin NDA.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated August 2, 2007

99.2 Press release dated August 2, 2007

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/ Robert J. Capetola
Name: Robert J. Capetola, Ph.D.
Title: President and Chief Executive Officer

Date: August 6, 2007



Discovery Labs Reports Second Quarter 2007 Financial Results

Warrington, PA — August 2, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced financial results for the second quarter ended June 30, 2007. 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, 2007, the Company reported a net loss of \$10.4 million (or \$0.12 per share) on 83.8 million weighted average common shares outstanding compared to a net loss of \$14.7 million (or \$0.24 per share) on 61.7 million weighted average common shares outstanding for the same period in 2006. Included in the net loss is a charge of \$1.7 million associated with stock-based compensation as a result of our adoption of Financial Accounting Standards No. 123(R) ("FAS 123(R)"). Additionally, the Company's cash burn from operating activities and debt service was \$8.2 million in the second quarter of 2007. As of June 30, 2007, the Company had 84.6 million common shares outstanding.

As of June 30, 2007, the Company had cash and marketable securities of \$40.8 million. During the second quarter of 2007, the Company completed a registered direct offering to institutional investors resulting in gross proceeds of \$30.2 million (\$28.1 million net). Additionally, under its Committed Equity Financing Facility (CEFF), the Company may, at its discretion, access capital through the issuance of up to approximately 7.1 million shares (not to exceed aggregate proceeds of \$40.5 million). Use of the CEFF is subject to certain conditions, including that the volume weighted average price of the Company's common stock during a draw down must be at least \$2.00 per share.

Also in the second quarter of 2007, the Company entered into a \$12.5 million secured credit facility with Merrill Lynch Capital to finance capital expenditures, of which \$9.0 million was immediately available and up to \$3.5 million will become available when the Company raises new capital through business development partnerships, stock offerings and other similar financings. Of the available \$9.0 million, approximately \$4.0 million was applied to prepay the Company's existing equipment financing indebtedness.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "Our top priority is to gain FDA approval of Surfaxin. We believe that considerable progress has been made in addressing the manufacturing stability failure and open CMC issues from the April 2006 Approvable Letter. Based on the progress to date, we remain confident that we are on track to file our formal response to the FDA in the October timeframe. With the continuing enhancements to our manufacturing and quality operations, the expansion of our pipeline and improved financial resources, we have strengthened our Company in 2007."

Selected Updates on SRT Pipeline Development:

- Recently, the Company initiated a Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering from Acute Respiratory Failure (ARF). This new trial will explore the expanded application of surfactant therapy to pediatric critical care medicine. This trial is intended to enroll approximately 180 patients and enrollment is currently active.
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- The Company is presently collaborating with Chrysalis Technologies on the development of a prototype aerosolization system to deliver Aerosurf to patients in the Neonatal Intensive Care Unit (NICU). The Company has also met with and received guidance from the FDA with respect to the design of the proposed Phase 2 clinical program. The Company and Chrysalis, together with third-party engineers and manufacturers, are presently collaborating on the development and optimization of this novel system as well as next generation drug device systems. The initial prototype development work, originally expected to be completed in the second half of 2007, is now anticipated to be completed in the first quarter of 2008. Based on the timing adjustment of the system development, initiation of our Phase 2 clinical program is now anticipated in the first quarter of 2008.

Second Quarter 2007 Operating Expenses:

Total operating expenses for the quarter ended June 30, 2007 were \$10.3 million compared to \$14.7 million for the same period in 2006. The decrease in this quarter compared to the same period last year is primarily due to a charge of \$4.8 million in 2006 associated with a corporate restructuring in April 2006, following receipt of an Approvable Letter from the FDA for Surfaxin and the process validation stability failure. For the second quarter of 2007, the components of the \$10.3 million operating expense included:

- manufacturing development expenses (included in research and development expenses) of \$2.9 million, including: (i) costs to operate the Company's manufacturing facility to support production of clinical and anticipated commercial drug supply for the Company's Surfactant Replacement Therapies (SRT) programs; (ii) continued investment in the Company's quality assurance and analytical chemistry capabilities to ensure compliance with current good manufacturing practices (cGMP); (iii) activities associated with developing data and other information necessary for the Company's formal response to the Surfaxin Approvable Letter; and (iv) activities to develop additional formulations of the Company's SRT;
 - research and development expenses (excluding manufacturing development activities) of \$3.9 million associated with infrastructure development, including clinical trial management, regulatory compliance, data management and biostatistics, and medical and scientific affairs activities as well as direct program expenses to advance the Company's SRT pipeline, including: (i) costs associated with developing data and other information necessary for the Company's formal response to the Surfaxin Approvable Letter; (ii) activities associated with the ongoing Phase 2 clinical trial to evaluate Surfaxin in children up to two years of age with ARF; and (iii) development activities related to Aerosurf™, the Company's proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP), to address premature infants at risk for respiratory failure;
 - general and administrative expenses of \$3.5 million, including costs associated with executive management, evaluation of various strategic business alternatives, financial and legal management and other administrative costs; and
 - \$1.7 million (classified in the amounts above as \$0.5 million in research and development and \$1.2 million in general and administrative) associated with stock-based employee compensation resulting from Financial Accounting Standards No. 123(R).
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Financial Results for the Six Months Ended June 30, 2007:

For the six months ended June 30, 2007, the Company reported a net loss of \$18.7 million (or \$0.24 per share) on 76.9 million weighted average common shares outstanding compared to a net loss of \$30.5 million (or \$0.50 per share) on 61.4 million weighted average common shares outstanding for the same period in 2006. Included in the net loss for the six months ended June 30, 2006 is a charge of \$4.8 million (or \$0.08 per share) associated with a corporate restructuring following receipt of the Approvable Letter for Surfaxin and the process validation stability failure.

Debt Arrangements at June 30, 2007:

The Company had \$9.3 million outstanding under its long-term loan with PharmaBio Development Inc., a strategic investment group of Quintiles Transnational Corp. The outstanding principal and all accrued interest since July 1, 2006, is due and payable on April 30, 2010. The Company may repay this loan in whole or in part at any time prior to April 2010 without prepayment penalty or premium.

The Company had \$4.2 million outstanding under its secured credit facility with Merrill Lynch Capital, of which \$1.7 million is classified as a current liability and \$2.5 million is classified as a long-term liability.

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 precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery Labs' lead product candidate, Surfaxin[®], 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. Among the factors which could affect Discovery Labs actual results and could cause results to differ from those contained in these forward-looking statements are the risk that Discovery Labs may not profitably develop and market its products, the risk that financial market conditions may change, the risk that Discovery Labs will not be able to attract or retain qualified personnel or timely provide for a successful sales and marketing organization, risks relating to the progress of Discovery Labs research and development, risks in the FDA or other regulatory agency review process generally, including that such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application or that approval by such regulatory agency may be withheld, delayed and/or limited by indications or other label limitations, risks that the Chemical, Manufacturing and Controls section of Discovery Labs New Drug Application will not satisfy the FDA, risks relating to the ability of Discovery Labs or Discovery Labs third party manufacturers and development partners to manufacture or provide Discovery Labs with adequate supplies of drug substances and expertise for completion of any of Discovery Labs clinical studies, risks related to the ability of Discovery Labs and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery Labs drug products with innovative aerosolization technologies, risks relating to drug manufacturing by Discovery Labs, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval process for any products that Discovery Labs may develop independently or with Discovery Labs collaboration arrangements, risks relating to the development by other companies of competing therapies and/or technologies, risks relating to reimbursement and health care reform, and risks relating to securities, product liability and other litigation. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Those associated 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)	
	2007	2006	2007	2006
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development (1)	6,794	5,911	12,216	13,524
General and administrative (1)	3,465	4,024	6,219	12,706
Restructuring charge	--	4,805	--	4,805
Total expenses	10,259	14,740	18,435	31,035
Operating loss	(10,259)	(14,740)	(18,435)	(31,035)
Other income / (expense)	(125)	45	(259)	545
Net loss	<u>\$ (10,384)</u>	<u>\$ (14,695)</u>	<u>\$ (18,694)</u>	<u>\$ (30,490)</u>
Net loss per common share	\$ (0.12)	\$ (0.24)	\$ (0.24)	\$ (0.50)
Weighted average number of common shares outstanding	83,825	61,652	76,907	61,411

(1) Expenses include a charge for stock-based employee compensation in accordance with the provisions of FAS 123(R), which the Company adopted on January 1, 2006. For the three and six months ended June 30, 2007, the charges associated with FAS 123(R) were \$1.7 million and \$2.4 million, respectively. For the three and six months ended June 30, 2006, the charges associated with FAS 123(R) were \$1.6 million and \$3.2 million, respectively.

Condensed Consolidated Balance Sheets

(in thousands)

	June 30,	December 31,
	2007	2006
ASSETS		
Current Assets:		
Cash and marketable securities	\$ 40,753	\$ 27,002
Prepaid expenses and other current assets	779	565
Total Current Assets	41,532	27,567
Property and equipment, net	5,618	4,794
Other assets	1,924	2,039
Total Assets	\$ 49,074	\$ 34,400
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 6,184	\$ 5,953
Capitalized leases and other liabilities	1,758	2,015
Total Current Liabilities	7,942	7,968
Long-Term Liabilities:		
Loan payable, including accrued interest	9,268	8,907
Capitalized leases and other liabilities	3,453	3,203
Total Liabilities	20,663	20,078
Stockholders' Equity	28,411	14,322
Total Liabilities and Stockholders' Equity	<u>\$ 49,074</u>	<u>\$ 34,400</u>



Discovery Labs Provides Update on Progress for Surfaxin® for RDS

Conference Call Today at 10:00 A.M.

Warrington, PA — August 2, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today reports progress in addressing previously-announced manufacturing and stability issues and the April 2006 FDA Approvable Letter (Approvable Letter), which focused on the Chemistry, Manufacturing and Controls (CMC) section of the New Drug Application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Discovery Labs remains on track to file its formal response to the Approvable Letter in the October 2007 timeframe, followed by an anticipated six-month review cycle by the FDA for potential approval of the Surfaxin NDA.

April 2006 Surfaxin Process Validation Stability Failure

Immediately following the April 2006 process validation stability failure, Discovery Labs conducted a comprehensive investigation into the stability failure, including identifying a most probable root cause, and remediated by executing a comprehensive corrective action and preventative action (CAPA) plan. As part of the investigation, Discovery Labs manufactured a series of investigational batches that supported the manufacture of three new process validation batches. These investigational batches are monitored using Discovery's most predictive stability-indicating method and continue to demonstrate acceptable stability, with the earliest manufactured batches continuing to demonstrate acceptable stability through twelve months, and the most-recently manufactured, through six months.

In February 2007, Discovery Labs completed the manufacture of the three new Surfaxin process validation batches that are a requirement for approval of the Surfaxin NDA. These process validation batches are subjected to comprehensive stability testing on pre-specified testing dates, in accordance with an established protocol that complies with ICH guidelines. Under the comprehensive testing protocol, these process validation batches have demonstrated acceptable stability through three months and continue to be monitored. The process validation batches must demonstrate acceptable stability through six-months under the comprehensive testing protocol before Discovery Labs can file its formal response to the Approvable Letter. Discovery Labs anticipates that six-month stability data will be available in October for inclusion in the formal response.

The new Surfaxin process validation batches were manufactured consistent with guidance obtained from the FDA at the December 2006 meeting. At that meeting, Discovery Labs presented information to the FDA regarding its comprehensive investigation and remediation of the April 2006 process validation stability failure. Included was information associated with the manufacture of the series of investigational batches, using a process consistent with that used to produce Surfaxin for Discovery Labs' successful RDS clinical trials. Discovery Labs applied the manufacturing process used to produce the investigational batches to produce the three new process validation batches.

April 2006 FDA Approvable Letter - Chemistry, Manufacturing and Controls

Discovery received an Approvable Letter for Surfaxin in April 2006 that primarily focused on the CMC section of the Surfaxin NDA. The Approvable Letter did not require any additional clinical trials, but requested additional information predominantly involving drug product specifications and stability, analytical methods and related controls. The CMC section of an NDA contains information to demonstrate that the drug product can be manufactured consistently to meet appropriate product quality requirements.

In December 2006, Discovery Labs met with the FDA to gain the clarity necessary to address key remaining CMC issues identified in the Approvable Letter. The FDA's guidance provided a defined pathway for Discovery Labs to generate additional data from selected experiments that are essential for approval of Surfaxin for the prevention of RDS in premature infants.

Discovery Labs believes it has made significant progress in addressing the outstanding issues identified in the Approvable Letter and is currently focused on completing the experiments, and compiling and analyzing the data for submission to the FDA. Discovery Labs believes that its progress to date supports the filing of the formal response to the Approvable Letter in the October 2007 timeframe.

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, including information being prepared for inclusion in Discovery Labs' formal response to the Approvable Letter and the potential results of both Discovery Labs' comprehensive manufacturing investigation and the ongoing release and stability testing of the investigational batches and the new process validation batches. Although Discovery Labs is encouraged by the progress that it believes it has made to date, the development of data and other relevant information for the formal response to the Approvable Letter, including the release and stability testing of the investigational batches and the new process validation batches, are ongoing and the final results of these efforts could vary materially from the observations and results obtained to date. Discovery Labs currently believes that it will succeed in submitting its formal response to the Approvable Letter, with six months of successful stability data for the new process validation batches, within the timeframe indicated above, subject, however, to a variety of risks, including that (i) Discovery Labs may not succeed in completing its experiments or developing the data and other information necessary for the formal response, (ii) the new process validation batches may in the future fail to meet designated stability or other release parameters, and (iii) Discovery Labs may identify unforeseen problems that have not yet been discovered. The reader of this release should understand that the failure to develop all necessary information required to respond to the Approvable Letter, including at least six months of stability data for the new process validation batches, could result in significant delays or additional requirements and potentially prevent the approval of Surfaxin or other Discovery Labs products.

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://investor.shareholder.com/media/eventdetail.cfm?mediaid=26687&c=DSCO&mediakey=50596D7D4BE16CECBA5B9FD9E893B75A&e=0> and www.discoverylabs.com. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 10288727.

About Surfaxin

Surfaxin, is a precision-engineered version of natural human lung surfactant and contains Discovery Labs' novel KL-4 peptide. Surfaxin, administered as a liquid-instillate, represents a potential alternative to the commercially available animal-derived surfactants. Data from Discovery Labs' pivotal, multinational SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS and results in improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. The SELECT and STAR (a supportive Phase 3 study) trials, as well as a pooled Phase 3 analysis, have been presented at several international medical meetings and the results from the two studies were published in *Pediatrics*. In addition, top-line results from Discovery Labs' Phase 2 clinical trial for the prevention and treatment of BPD suggested that infants treated with up to five incremental standard doses of Surfaxin tended to have a lower incidence of death or BPD, a higher survival rate through 36 weeks post-menstrual age, and fewer days on mechanical ventilation. Discovery Labs recently initiated a Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering from Acute Respiratory Failure (ARF). This new trial will explore the expanded application of surfactant therapy to pediatric critical care medicine.

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