

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**

**November 6, 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 November 6, 2007, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the third quarter ended September 30, 2007, and providing selected updates concerning Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and the completion of a new research and analytical laboratory in the Company’s Warrington, PA headquarters. 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 November 6, 2007, the Company held a conference call to discuss the financial results for the third quarter ended September 30, 2007. On the call, the Company provided an estimate of aggregate cash outflows from operating and investing activities for the fourth fiscal quarter of 2007 of approximately \$9.0-9.5 million.

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

(d) Exhibits

99.1 Press release dated November 6, 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: November 6, 2007





## Discovery Labs Reports Third Quarter 2007 Financial Results

**Warrington, PA — November 6, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today announced financial results for the third quarter ended September 30, 2007. The Company will host a conference call today at 10:00 AM EST. **The call in number is 866-332-5218.**

For the quarter ended September 30, 2007, the Company reported a net loss of \$9.3 million (or \$0.11 per share) on 84.6 million weighted average common shares outstanding compared to a net loss of \$8.0 million (or \$0.13 per share) on 62.3 million weighted average common shares outstanding for the same period in 2006. Included in the net loss is a charge of \$1.1 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 \$7.7 million in the third quarter of 2007. As of September 30, 2007, the Company had 84.7 million common shares outstanding.

As of September 30, 2007, the Company had cash and marketable securities of \$33.1 million. In October, the company completed a financing pursuant to its Committed Equity Financing Facility (CEFF) resulting in proceeds of \$5.0 million from the issuance of approximately 1.9 million shares of common stock. Under the CEFF, the Company may, at its discretion, access capital through the issuance of up to approximately 5.2 million shares (not to exceed aggregate proceeds of \$35.5 million). Use of the CEFF is subject to certain conditions, including that, to initiate a draw down, the volume weighted average price of the Company's common stock on the trading day immediately preceding the draw down must be at least \$2.00 per share.

### Select Company Updates:

- The Company recently submitted to the FDA its formal response to the April 2006 Approvable Letter for Surfaxin<sup>®</sup> for the prevention of Respiratory Distress Syndrome (RDS) in premature infants (Approvable Letter). In addition, the Company announced in October that its new Surfaxin process validation batches demonstrated acceptable stability at six-months under the Company's comprehensive stability testing protocol. The formal response includes the six-month stability data on the new Surfaxin process validation batches and addresses the outstanding CMC (chemistry, manufacturing and controls) matters identified in the Approvable Letter. Assuming that the FDA accepts the submission as a complete response, the Company anticipates that the FDA will designate the formal response as a Class II submission, thereby allowing for a six-month review period with a target approval date in the second quarter of 2008.
  - In October, the Company completed the construction of a new research and analytical laboratory in its Warrington, PA corporate headquarters. The new laboratory will consolidate the analytical and operational activities that are presently located in Doylestown, PA and Mountain View, CA, including analytical testing of raw materials and commercial and clinical drug product supply, as well as research and development of the Company's aerosol SRT and other novel formulations. The consolidation of scientific and analytical resources into one facility will allow the Company to leverage professional and scientific expertise and improve both operational efficiency and financial economics.
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The investment in the new laboratory will be \$3.3M (\$2.6M is reflected on the balance sheet as property and equipment at September 30, 2007 with the remainder anticipated in Q4). The Company anticipates that 95% of the total project will be financed utilizing: (i) the existing secured credit facility with Merrill Lynch Capital; (ii) \$650,000 from the State of Pennsylvania (includes a \$500,000 Equipment Loan, and grants of up to \$150,000 through the Opportunities Grant Program and Customized Job Training Funds); and (iii) \$400,000 of landlord contributions under the Company's existing lease agreement.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "Surfaxin has the potential to raise the standard of care for premature infants and, we believe, is the foundation on which to build an important respiratory franchise. The Company's top priority is to gain FDA approval of Surfaxin. Filing of our response to the Approvable Letter and achieving six-months stability on our new Surfaxin process validation batches are important milestones towards achieving that goal.

Aerosurf™, aerosolized SRT delivered through non-invasive methods, holds the promise to significantly expand the use of surfactants in neonatal and pediatric medicine. The recent consolidation of our labs will permit our scientific and development experts to collaborate more efficiently in the management of our pipeline, specifically Aerosurf and our aerosolized SRT."

### **Third Quarter 2007 Operating Expenses:**

Total operating expenses for the quarter ended September 30, 2007 were \$9.3 million compared to \$8.0 million for the same period in 2006. The increase in this quarter compared to the same period last year is primarily due to investment in: (i) quality assurance and analytical chemistry capabilities to ensure compliance with current good manufacturing practices (cGMP); (ii) costs associated with preparation of the Company's formal response to the Approvable Letter; and (iii) costs associated with the Company's recently initiated Phase 2 clinical trial to evaluate the use of Surfaxin in children up to two years of age with Acute Respiratory Failure. For the third quarter of 2007, the components of the \$9.3 million operating expense included:

- manufacturing development expenses (included in research and development expenses) of \$3.1 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 cGMP; (iii) activities associated with developing data and other information necessary for the Company's formal response to the Approvable Letter; and (iv) activities to develop additional formulations of the Company's SRT;
  - research and development expenses (excluding manufacturing development activities) of \$3.1 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 Approvable Letter; (ii) activities associated with the ongoing Phase 2 clinical trial to evaluate Surfaxin in children up to two years of age with Acute Respiratory Failure; 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; and
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- general and administrative expenses of \$3.1 million, including costs associated with executive management, evaluation of various strategic business alternatives, financial and legal management and other administrative costs.
- \$1.1 million, classified in the amounts above as \$0.3 million in research and development and \$0.8 million in general and administrative, is associated with stock-based employee compensation resulting from Financial Accounting Standards No. 123(R).

**Debt Arrangements at September 30, 2007:**

The Company had \$9.5 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 has a \$12.5 million secured credit facility with Merrill Lynch Capital to finance capital expenditures, of which \$9.0 million was initially immediately available and up to \$3.5 million will become available as the Company raises new capital through business development partnerships, stock offerings and other similar financings. As of September 30, 2007, \$4.9 million is outstanding, of which \$2.1 million is classified as a current liability and \$2.8 million is classified as a long-term liability. In the third quarter, the Company used \$1.3 million under this facility, primarily to finance the new laboratory. As of September 30, 2007, \$3.5 million is currently available for use under this facility.

**Financial Results for the Nine Months Ended September 30, 2007:**

For the nine months ended September 30, 2007, the Company reported a net loss of \$28.0 million (or \$0.35 per share) on 79.5 million weighted average common shares outstanding compared to a net loss of \$38.5 million (or \$0.62 per share) on 61.7 million weighted average common shares outstanding for the same period in 2006. Included in the net loss for the nine months ended September 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 and the process validation stability failure.

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## 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<sup>®</sup>, 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<sup>™</sup>, 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](http://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 risk factors which could affect Discovery Labs actual results and could cause results to differ from those contained in these forward-looking statements are the risks that: Discovery Labs may be unable to profitably develop and market its products; financial market conditions may change; Discovery Labs may not be able to raise additional capital or enter into additional collaboration agreements; Discovery Labs may not be able to attract or retain qualified personnel or timely provide for successful sales and marketing activities; Discovery Labs' research and development efforts may not progress; Discovery Labs may not be successful 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 accepting an application or may withhold, delay and/or limit marketing a drug product by indication or impose other label limitations; Discovery Labs' recently-submitted response to the Approvable Letter may not satisfy the FDA; Discovery Labs or its third party manufacturers and development partners may be unable to manufacture or provide adequate supplies of drug substances and expertise to allow for completion of any of Discovery Labs clinical studies; Discovery Labs and its collaborators may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs drug products with innovative aerosolization technologies; Discovery Labs may not be able to successfully manufacture its drug product candidates; Discovery Labs' significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and efforts to gain regulatory approval for any products that it may develop (independently or in connection with collaboration arrangements) may not succeed; other companies may develop competing therapies and/or technologies; reimbursement and health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in 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

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	(unaudited)		(unaudited)	
	2007	2006	2007	2006
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development (1)	6,184	5,204	18,400	18,728
General and administrative (1)	3,147	2,723	9,366	15,429
Restructuring charge	--	--	--	4,805
Total expenses	9,331	7,927	27,766	38,962
Operating loss	(9,331)	(7,927)	(27,766)	(38,962)
Other income / (expense)	(16)	(71)	(275)	474
Net loss	\$ (9,347)	\$ (7,998)	\$ (28,041)	\$ (38,488)
Net loss per common share	\$ (0.11)	\$ (0.13)	\$ (0.35)	\$ (0.62)
Weighted average number of common shares outstanding	84,642	62,312	79,485	61,703

(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 nine months ended September 30, 2007, the charges associated with FAS 123(R) were \$1.1 million (\$0.3 million in R&D and \$0.8 million in G&A) and \$3.5 million (\$1.1 million in R&D and \$2.4 million in G&A), respectively. For the three and nine months ended September 30, 2006, the charges associated with FAS 123(R) were \$0.9 million (\$0.3 million in R&D and \$0.6 million in G&A) and \$4.1 million (\$1.2 million in R&D and \$2.9 million in G&A), respectively.

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

	September 30,	December 31,
	2007	2006
<b>ASSETS</b>		
Current Assets:		
Cash and marketable securities	\$ 33,086	\$ 27,002
Prepaid expenses and other current assets	298	565
Total Current Assets	33,384	27,567
Property and equipment, net	7,186	4,794
Other assets	1,778	2,039
Total Assets	\$ 42,348	\$ 34,400
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 6,819	\$ 5,953
Capitalized leases and other liabilities	2,146	2,015
Total Current Liabilities	8,965	7,968
Long-Term Liabilities:		
Loan payable, including accrued interest	9,452	8,907
Capitalized leases and other liabilities	3,663	3,203
Total Liabilities	22,080	20,078
Stockholders' Equity	20,268	14,322
Total Liabilities and Stockholders' Equity	\$ 42,348	\$ 34,400