

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**

**February 14, 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 February 14, 2008, Discovery Laboratories, Inc. (the "Company") issued a press release announcing financial results for the fourth quarter ended December 31, 2007, and providing selected updates concerning the Company's efforts to gain approval of its New Drug Application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In November 2007, the U.S. Food and Drug Administration (FDA) accepted Discovery Labs' Complete Response to the April 2006 Approvable Letter for Surfaxin<sup>®</sup> (lucinactant), for the prevention of RDS in premature infants. The FDA has established May 1, 2008 as its target date to complete its review of the Surfaxin NDA. The Company also provided updates regarding the Phase 2 clinical trial for Surfaxin in children up to the age of two with Acute Respiratory Failure (ARF). 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 February 14, 2008, the Company held a conference call to discuss the financial results for the fourth quarter ended December 31, 2007. On the call, the Company provided an estimate of the anticipated loss for the first quarter of 2008 of \$13.0 - \$14.0 million, which includes certain non-cash charges, such as charges associated with stock-based compensation in accordance with Financial Accounting Standards No. 123R. The Company anticipates aggregate cash outflows from operating and investing activities for the first fiscal quarter of 2008 of approximately \$12 million, representing an increase of approximately \$2.5 - \$3.0 million from the guidance provided for the fourth quarter of 2007. The anticipated increase in cash outflows is expected to be used primarily to advance the development of Aerosurf™, the Company's proprietary aerosolized SRT (Surfactant Replacement Therapies) for the prevention and treatment of infants at risk for respiratory failure, and establish its own U.S. commercial sales and marketing organization specialized in neonatal and pediatric indications.

(d) Exhibits

99.1 Press release dated February 14, 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.**

By: /s/ Robert J. Capetola

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Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer

Date: February 14, 2008



## Discovery Labs Reports Fourth Quarter 2007 Financial Results

**Warrington, PA — February 14, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today announced financial results for the fourth quarter ended December 31, 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 December 31, 2007, the Company reported a net loss of \$12.0 million (or \$0.14 per share) on 88.5 million weighted average common shares outstanding compared to a net loss of \$7.8 million (or \$0.12 per share) on 66.2 million weighted average common shares outstanding for the same period in 2006. Included in the fourth quarter 2007 net loss is a charge of \$1.8 million associated with stock-based compensation per Financial Accounting Standards No. 123R (“FAS 123(R)”), \$0.6 million for the consolidation of operating activities from California to the new laboratory recently completed in the Warrington, PA headquarters facility, and an adjustment to depreciation expense per a change in accounting estimates based on an evaluation of useful lives of the Company’s fixed assets. The Company’s fourth quarter 2007 cash burn from operating activities, capital expenditures and debt arrangements was \$8.6 million. As of December 31, 2007, the Company had 96.6 million common shares outstanding.

As of December 31, 2007, the Company had cash and marketable securities of \$53.0 million and approximately 5.2 million shares available for issuance under the Company’s Committed Equity Financing Facility (CEFF) for future financings (not to exceed \$35.5 million). In the fourth quarter of 2007, the Company raised \$30 million associated with: (i) a registered direct offering to institutional investors resulting in gross proceeds of \$25.0 million (\$23.6 million net) from the sale of 10.0 million shares of common stock and (ii) a financing pursuant to the CEFF resulting in proceeds of \$5.0 million from the issuance of approximately 1.9 million shares of common stock.

### Select Company Updates:

- In November 2007, the U.S. Food and Drug Administration (FDA) accepted Discovery Labs’ Complete Response to the April 2006 Approvable Letter for Surfaxin<sup>®</sup> (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established May 1, 2008 as its target date to complete its review of the Surfaxin New Drug Application (NDA). The Complete Response addressed the outstanding CMC (chemistry, manufacturing and controls) matters identified in the Approvable Letter and included six month stability data on the Surfaxin process validation batches which were manufactured in January / February 2007. The Company has tested and is continuing to perform on-going stability analysis on these process validation batches using a comprehensive stability testing protocol that complies with International Conference on Harmonization (ICH) guidelines. The Company continues to be satisfied with the process validation stability data generated to date.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, “Surfaxin has the potential to raise the standard of care for treatment of premature infants and, along with Aerosurf<sup>™</sup>, is the foundation on which we plan to build an important respiratory franchise. Aerosurf, our aerosolized SRT delivered through non-invasive methods, holds the promise to significantly expand the use of surfactants in neonatal and pediatric medicine. Both Surfaxin and Aerosurf are based on the Company’s novel KL-4 surfactant technology.

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The Company's top priority is to gain FDA approval of Surfaxin. We also intend to expand Surfaxin use through life-cycle management and continue the development of Aerosurf into Phase 2 clinical trials. To prepare for the anticipated approval of Surfaxin, the Company is planning to establish its own U.S. commercial sales and marketing organization specialized in neonatal and pediatric indications. The Company is also pursuing potential collaboration arrangements with international partners to co-develop and/or co-commercialize its neonatal and pediatric pipeline for Surfaxin and Aerosurf."

- The Company is currently conducting a Phase 2 clinical trial evaluating using Surfaxin in children up to the age of two with Acute Respiratory Failure (ARF). The objective of the study is to evaluate the safety and tolerability of Surfaxin administration and to assess whether such treatment can decrease the duration of mechanical ventilation in young children with ARF. ARF occurs when lung tissue is significantly damaged, most commonly by a viral infection of the lung. This disorder is largely caused by a seasonal virus, such as influenza or Respiratory Syncytial Virus (RSV). Currently, patient enrollment has been slower than expected and, as a result, the Company is extending the period for patient enrollment through an additional viral season at already established sites in the southern hemisphere. The Company intends to provide an update on this clinical trial in the Company's third quarter business update.

#### **Fourth Quarter 2007 Net Loss:**

The net loss for the quarter ended December 31, 2007 was \$12.0 million compared to \$7.8 million for the same period in 2006. The primary components of the \$12.0 million net loss, and the increase versus last year, included:

- manufacturing development expenses (included in research and development expenses) of \$3.5 million, including: (i) continued investment in manufacturing, quality assurance and analytical chemistry capabilities to ensure compliance with current good manufacturing practices (cGMP) to support the production of clinical and anticipated commercial drug supply for the Company's SRT pipeline; (ii) activities to develop additional formulations of the Company's SRT; and (iii) activities to develop aerosolization systems, including the aerosol generating device, the disposable dose delivery packet and patient interface system necessary to administer Aerosurf. These costs increased by \$1.2 million compared to the same period last year.
  - research and development expenses (excluding manufacturing development activities) of \$4.3 million associated with internal development capabilities (scientific management, clinical trial management, regulatory compliance, data management and biostatistics, and medical affairs) as well as direct program expenses to develop and advance the Company's SRT pipeline, primarily (i) Aerosurf, the Company's proprietary aerosolized SRT for the prevention and treatment of infants at risk for respiratory failure and the potential to obviate the need for endotracheal intubation and conventional mechanical ventilation, and (ii) activities associated with the ongoing Phase 2 clinical trial to evaluate Surfaxin in children up to two years of age with ARF. These costs increased by \$1.6 million compared to the same period last year.
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- general and administrative expenses of \$4.4 million, including costs associated with executive, financial and legal management, evaluation of various strategic business alternatives, and other administrative costs. Also included are pre-launch commercialization activities related to the Company's plans to build its own specialty pulmonary United States sales and marketing organization to focus on the commercial and medical promise of Surfaxin and Aerosurf to address respiratory therapies for neonatal and pediatric diseases. These costs increased by \$1.4 million compared to the same period last year.
- \$1.8 million, included and classified in the amounts above as \$0.6 million in research and development and \$1.2 million in general and administrative, associated with stock-based employee compensation resulting from FAS 123(R). These costs increased by \$0.5 million compared to the same period last year.
- The Company reviews the estimated useful lives of its fixed assets on an ongoing basis and, as a result, changed its estimates of the related useful lives to better reflect the estimated periods during which these assets will remain in service. This resulted in a non-recurring charge to depreciation expense in the fourth quarter of 2007 of \$0.4 million, included and classified in the amounts above as \$0.2 million in research and development and \$0.2 million in general and administrative.

#### **Debt Arrangements at December 31, 2007:**

The Company had \$9.6 million outstanding under its long-term loan with PharmaBio Development Inc., a strategic investment group of Quintiles Transnational Corp. The outstanding principal and all interest accrued from 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 made available immediately and up to \$3.5 million becomes available as the Company raises new capital through business development partnerships, equity and other similar financings. In the fourth quarter of 2007, the Company raised an aggregate of \$30 million through equity financings and an additional \$3.0 million became available for use under the credit facility. In the fourth quarter of 2007, the Company used \$1.3 million under this facility, primarily to finance construction of a new research and analytical laboratory in its Warrington, Pennsylvania corporate headquarters. As of December 31, 2007, \$5.6 million is outstanding (\$2.6 million is classified as a current liability and \$3.0 million is classified as a long-term liability) and \$5.1 million remained available for use under this facility.

#### **Financial Results for the Twelve Months Ended December 31, 2007:**

For the twelve months ended December 31, 2007, the Company reported a net loss of \$40.0 million (or \$0.49 per share) on 81.7 million weighted average common shares outstanding compared to a net loss of \$46.3 million (or \$0.74 per share) on 62.8 million weighted average common shares outstanding for the same period in 2006. Included in the net losses for the twelve months ended December 31, 2007 and 2006 are charges of \$5.2 million (or \$0.06 per share) and \$5.5 million (or \$0.09 per share), respectively, associated with stock-based compensation per FAS 123(R). Also, included in the net loss for the twelve months ended December 31, 2006 is a charge of \$4.8 million (or \$0.08 per share) associated with a corporate restructuring following receipt of the 2006 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' 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 (including strategic alliances for development or commercialization of SRT); 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. 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

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

	Three Months Ended December 31, (unaudited)		Twelve Months Ended December 31,	
	2007	2006	2007	2006
	2007	2006	2007	2006
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development (1)	7,800	4,988	26,200	23,716
General and administrative (1)	4,381	2,957	13,747	18,386
Restructuring charge	--	--	--	4,805
Total expenses	12,181	7,945	39,947	46,907
Operating loss	(12,181)	(7,945)	(39,947)	(46,907)
Other income / (expense)	217	100	(58)	574
Net loss	\$ (11,964)	\$ (7,845)	\$ (40,005)	\$ (46,333)
Net loss per common share	\$ (0.14)	\$ (0.12)	\$ (0.49)	\$ (0.74)
Weighted average number of common shares outstanding	88,469	66,195	81,731	62,767

(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 twelve months ended December 31, 2007, the charges associated with FAS 123(R) were \$1.8 million (\$0.6 million in R&D and \$1.2 million in G&A) and \$5.2 million (\$1.7 million in R&D and \$3.5 million in G&A), respectively. For the three and twelve months ended December 31, 2006, the charges associated with FAS 123(R) were \$1.3 million (\$0.4 million in R&D and \$0.9 million in G&A) and \$5.5 million (\$1.7 million in R&D and \$3.8 million in G&A), respectively.

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

<u>ASSETS</u>	December 31, 2007	December 31, 2006
<b>Current Assets:</b>		
Cash and marketable securities	\$ 53,007	\$ 26,402
Prepaid expenses and other current assets	611	565
Total Current Assets	53,618	26,967
Property and equipment, net	7,069	4,794
Restricted Cash	600	600
Other assets	1,457	2,039
Total Assets	\$ 62,744	\$ 34,400
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
<b>Current Liabilities:</b>		
Accounts payable and accrued expenses	\$ 7,844	\$ 5,953
Capitalized leases and other current liabilities	2,625	2,015
Total Current Liabilities	10,469	7,968
<b>Long-Term Liabilities:</b>		
Loan payable, including accrued interest	9,633	8,907
Capitalized leases and other liabilities	3,861	3,203
Total Liabilities	23,963	20,078
<b>Stockholders' Equity</b>	38,781	14,322
Total Liabilities and Stockholders' Equity	\$ 62,744	\$ 34,400