

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, 2006**

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 8, 2006, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended September 30, 2006, and providing selected updates on the Company’s progress since the end of the second fiscal quarter in 2006. 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 heret 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 expressly set forth by specific reference in any such filings.

**Item 8.01. Other Events.**

On November 6, 2006, the Company issued a press release to announce that the United States District Court for the Eastern District of Pennsylvania dismissed, without prejudice, the Consolidated Amended Class Action Complaint filed on August 9, 2006 against the Company and two of its executive officers. The plaintiffs were granted leave to file an amended Consolidated Amended Complaint by November 30, 2006. The press release is filed as Exhibit 99.2 hereto and is incorporated herein by reference.

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

- (d) Exhibits
- 99.1 Press Release dated November 8, 2006.
- 99.2 Press Release dated November 6, 2006.

**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: November 9, 2006

By: /s/ Robert J. Capetola

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Robert J. Capetola, Ph.D.  
President and Chief Executive Officer

## Discovery Labs Reports Third Quarter 2006 Financial Results

**Warrington, PA — November 8, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today announced financial results for the third quarter ended September 30, 2006. The Company will host a conference call Thursday, November 9<sup>th</sup> at 10:00 AM EST. **The call in number is 866-332-5218.**

For the quarter ended September 30, 2006, the Company reported, on a GAAP basis, a net loss of \$8.0 million, or \$0.13 per share, on 62.3 million weighted average common shares outstanding compared to a net loss of \$10.4 million (or \$0.19 per share) on 54.5 million weighted average common shares outstanding for the same period in 2005. Included in the GAAP net loss for the third quarter of 2006 is a charge of \$0.9 million (or \$0.02 per share) associated with stock-based employee compensation resulting from the adoption of Financial Accounting Standards No. 123(R) (FAS 123(R)) in 2006. Excluding this charge, the non-GAAP net loss for the quarter ended September 30, 2006 was \$7.1 million (or \$0.11 per share). As of September 30, 2006, the Company had 62.4 million common shares outstanding.

As of September 30, 2006, the Company had cash and marketable securities of \$19.7 million, compared to \$27.3 million as of June 30, 2006, a decrease of \$7.6 million. The decrease is primarily due to net cash used in operating activities. In October and November the Company entered into two financings under its Committed Equity Financing Facility (CEFF) that have generated proceeds of approximately \$5.0 million from the issuance of approximately 2.4 million shares of common stock. The Company currently has approximately 8.2 million shares available for issuance under the CEFF for future financings (not to exceed \$42.9 million).

At September 30, 2006, the Company had an \$8.5 million loan with PharmaBio Development Inc. (PharmaBio), an investment group of Quintiles Transnational Corp., that was scheduled to mature on December 31, 2006. In October 2006, the loan was restructured to provide, among other things, that all principal and interest is now due on April 30, 2010. In connection with the restructuring, Discovery and PharmaBio entered into a Warrant Agreement, pursuant to which PharmaBio has the right to purchase during a 7-year term 1.5 million shares of the Company's common stock at an exercise price of \$3.58 per share. Under the Company's capital lease financing arrangement with General Electric Capital Corporation (GECC), as of September 30, 2006, \$4.8 million was outstanding of which \$1.9 million is classified as a current liability and \$2.9 million as a long-term liability.

In addition, selected updates on the Company's recent progress include:

- On September 28, 2006, the Company submitted an information package and requested a meeting with the U.S. Food and Drug Administration (FDA). The package covers items identified in the April 2006 Approvable Letter that the Company received from the FDA, which primarily focused on the Chemistry, Manufacturing and Controls (CMC) portion of our new drug application (NDA), and provides information about the Company's comprehensive investigation and remediation of the April 2006 Surfaxin<sup>®</sup> process validation stability failure. The purpose of the meeting is to clarify the information requested by the FDA in the Approvable Letter and reach agreement on the appropriate path to potentially gain approval of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA meeting has been scheduled for December 21, 2006.
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- In October, the Company announced encouraging preliminary results from its Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS. The study results suggest that Surfaxin therapy may potentially represent a novel therapeutic option for infants at risk for or suffering from BPD. Improved outcomes were observed with Surfaxin including a lower incidence of death or BPD in patients receiving the Surfaxin standard dose as compared with the control group receiving standard of care. The FDA previously granted Orphan Drug Status and Fast Track designations for Surfaxin for the prevention and treatment of BPD. Presently there are no approved therapies for this disease.
- In October, the Company announced that additional clinical data from the SELECT and STAR Phase 3 trials for Surfaxin for the prevention of RDS in premature infants demonstrate that Surfaxin-treated infants require significantly less invasive re-intubation and experience improved key clinical outcomes compared to those treated with the current market leading animal-derived surfactants.
- On November 6, 2006 the Company announced that the United States District Court for the Eastern District of Pennsylvania dismissed, without prejudice, the Consolidated Amended Class Action Complaint filed on August 9, 2006 against the Company and two of its executive officers and granted plaintiffs leave to file an amended Consolidated Amended Complaint by November 30, 2006.

### **Review of Operating Results - Third Quarter Ended September 30, 2006**

The Company reported, on a GAAP basis, a net loss of \$8.0 million for the quarter ended September 30, 2006, a decrease of \$2.4 million compared to the same period in 2005. Excluding a charge of \$0.9 million for stock-based employee compensation associated with the Company's adoption of FAS 123(R) in 2006, the non-GAAP net loss for the quarter ended September 30, 2006 was \$7.1 million compared to \$10.4 million for the same period in 2005, a decrease of \$3.3 million. The primary components of the third quarter 2006 loss include:

- (i) manufacturing development expenses (included in research and development expenses) for the quarter ended September 30, 2006 were \$2.2 million, a decrease of \$0.8 million compared to the same period in 2005. Manufacturing development includes (1) costs associated with operating the Company's manufacturing facility in Totowa, New Jersey (which the Company acquired from its then-contract manufacturer, Laureate Pharma, Inc. (Laureate), in December 2005), to support the production of clinical and anticipated commercial drug supply for the Company's SRT programs; (2) continued investment in the Company's quality assurance and analytical chemistry capabilities to assure current good manufacturing practices (cGMP); and (3) costs associated with the ongoing comprehensive investigation and analysis of the April 2006 Surfaxin process validation stability failure and remediation of the Company's related manufacturing issues. Expenditures in the quarter ended September 30, 2005 primarily represented Laureate manufacturing service charges and direct costs for the manufacture of Surfaxin, as well as costs of improvements and enhancements to the manufacturing operations.
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- (ii) research and development expenses (excluding manufacturing development activities) for the quarter ended September 30, 2006 were \$2.7 million, no change compared to the same period in 2005. Expenditures in the third quarter of 2006 were primarily associated with costs incurred for (1) regulatory activities related to the April 2006 Approvable Letter for Surfaxin for RDS and the process validation stability failure; (2) clinical and data management activities related to the Phase 2 clinical trial of Surfaxin for the prevention and treatment of BPD; (3) engineering and development activities (in conjunction with our strategic alliance with Chrysalis Technologies, Inc., a division of Philip Morris USA) related to Aerosurf™, the Company's proprietary SRT in aerosolized form administered through nasal continuous positive airway pressure (nCPAP), for the prevention and treatment of infants at risk for respiratory failure; and (4) research and development activities to expand the application of the Company's technology in other respiratory conditions and explore improved formulations; and
- (iii) general and administrative expenses for the quarter ended September 30, 2006 were \$2.1 million, a decrease of \$2.7 million compared to the same period in 2005. Expenses in 2006 include, but are not limited to, the costs of executive management, cost to defend the recently dismissed Class Action lawsuit, evaluating various strategic business alternatives, financial and legal management and other administrative costs. Included in 2005 are costs associated with building a United States commercial infrastructure. The decrease compared to last year primarily reflects the Company's decision, in response to the April 2006 Approvable Letter and the Surfaxin process validation stability failure, to discontinue this capability.

For the nine months ended September 30, 2006, the Company reported, on a GAAP basis, a net loss of \$38.5 million, (or \$0.62 per share), on 61.7 million weighted average common shares outstanding compared to a net loss of \$29.5 million, (or \$0.56 per share), on 52.8 million weighted average shares outstanding for the same period in 2005. Included in the GAAP net loss for the nine months ended September 30, 2006 is a charge of \$4.1 million (or \$0.06 per share) for stock-based compensation associated with FAS 123(R) and a restructuring charge of \$4.8 million (or \$0.08 per share) related to the staff reductions and the close-out of certain commercial programs as a result of the adjusted timeline for regulatory approval and commercial launch of Surfaxin for the prevention of RDS in premature infants. Excluding these charges, the non-GAAP net loss for the nine months ended September 30, 2006 was \$29.6 million (or \$0.48 per share).

### **Use of Non-GAAP Financial Measures**

Discovery adopted FAS 123(R) on January 1, 2006 using the modified prospective method, which resulted in the recognition of stock compensation expenses in the statement of operations for the three and nine months ended September 30, 2006 without adjusting the same prior year periods. Discovery uses non-GAAP net loss data to improve its analysis of operational results and trends. Discovery's management also uses these non-GAAP figures to make financial and operational decisions as these numbers exclude non-operational activities. Discovery believes that presentation of results excluding non-cash compensation expense and restructuring charges may provide meaningful supplemental information to both management and investors. These measures should not be considered an alternative to measurements required by GAAP, such as net loss and net loss per share, and should not be considered measures of our liquidity. A reconciliation between non-GAAP financial measures and GAAP financial measures is included in a footnote to the Statement of Operations accompanying this press release.

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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's technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery believes that its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting premature infants, children and adults.

Discovery's 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 the prevention and treatment of Bronchopulmonary Dysplasia in premature infants. Aerosurf™, Discovery's aerosolized SRT, is being developed initially to treat premature infants suffering from respiratory disorders and is intended to obviate the need for intubation and conventional mechanical ventilation. Discovery's SRT pipeline also includes programs addressing Acute Lung Injury, Acute Respiratory Failure, Cystic Fibrosis, Acute Respiratory Distress Syndrome, and other respiratory conditions. **For more information, please visit our newly redesigned corporate website at [www.Discoverylabs.com](http://www.Discoverylabs.com).**

*To the extent that statements in this press release 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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, 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's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for aerosol and Surfactant Replacement Therapies), the risk that Discovery will not be able to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all, the risk that approval by the FDA or other health regulatory authorities of any applications filed by Discovery may be withheld, delayed and/or limited by indications or other label limitations, the risk that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by Discovery for any such drug product, risks that the Chemistry, Manufacturing and Controls (CMC) section of Discovery's New Drug Application will not satisfy the FDA, risk in the FDA or other regulatory agency review process generally, risks relating to the ability of Discovery or Discovery's third party contract manufacturers and development partners to manufacture or provide Discovery with adequate supplies of drug substance, drug products and expertise for completion of any of Discovery's clinical studies, risks relating to drug manufacturing by Discovery, risks relating to the integration of manufacturing operations into Discovery's existing operations, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, risks relating to the ability of Discovery and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery's drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with Discovery's collaboration arrangements, and risks relating to the development of competing therapies and/or technologies by other companies. 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'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.*

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**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)	
	2006	2005	2006	2005
Revenues from collaborative agreements	\$ -	\$ 20	\$ -	\$ 105
Operating expenses:				
Research and development (1)	5,204	5,676	18,728	16,660
General and administrative (1)	2,723	4,817	15,429	13,182
Restructuring charge	--	--	4,805	--
Total operating expenses	7,927	10,493	38,962	29,842
Operating loss	(7,927)	(10,473)	(38,962)	(29,737)
Other income / (expense)	(71)	67	474	189
Net loss	<u>\$ (7,998)</u>	<u>\$ (10,406)</u>	<u>\$ (38,488)</u>	<u>\$ (29,548)</u>
Net loss per common share	\$ (0.13)	\$ (0.19)	\$ (0.62)	\$ (0.56)
Weighted average number of common shares outstanding	62,312	54,476	61,703	52,844

(1) Included in expenses for the three and nine months ended September 30, 2006 are charges of \$0.9 million (\$0.3 million classified as research and development and \$0.6 million classified as general and administrative) (or \$0.02 per share) and \$4.1 million (\$1.2 million classified as research and development and \$2.9 million classified as general and administrative) (or \$0.06 per share), respectively, associated with stock-based employee compensation in accordance with the provisions of SFAS No. 123(R), which the Company adopted on January 1, 2006.

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

	September 30,	December 31,
	2006	2005
	(unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and marketable securities	\$ 19,723	\$ 50,908
Prepaid expenses and other current assets	278	560
Total Current Assets	20,001	51,468
Property and equipment, net	4,604	4,322
Other assets	216	218
Total Assets	<u>\$ 24,821</u>	<u>\$ 56,008</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 6,867	\$ 7,540
Credit facility (2)	8,500	8,500
Capitalized leases and other liabilities	1,922	1,568
Total Current Liabilities	17,289	17,608
Long-Term Liabilities:		
Capitalized leases and other liabilities	3,489	3,562
Total Liabilities	20,778	21,170
Stockholders' Equity	4,043	34,838
Total Liabilities and Stockholders' Equity	<u>\$ 24,821</u>	<u>\$ 56,008</u>

(2) In October 2006, the Company restructured its \$8.5 million loan with Quintiles Transnational Corp. Payment of the \$8.5 million loan principal, originally due December 31, 2006, has now been extended as a lump sum payment due on April 30, 2010.

## Discovery Labs Announces Federal Court's Dismissal of Class Action Law Suits

**Warrington, PA — November 6, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO)** a biotechnology company focused on developing its proprietary surfactant replacement therapies to address various respiratory conditions, announced today that the United States District Court for the Eastern District of Pennsylvania dismissed, without prejudice, the Consolidated Amended Class Action Complaint filed on August 9, 2006 against the Company and two of its executive officers.

The Complaint alleged violations of Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act), Rule 10b-5 and Section 20(a) of the Exchange Act in connection with various public statements made by the Company. The Court's decision to dismiss the Complaint is based on several grounds, including plaintiffs' failure to set forth particularized facts giving rise to a strong inference that defendants acted with a conscious disregard of the truth or recklessness. In the Court's dismissal without prejudice, the plaintiffs were granted leave to file an amended Consolidated Amended Complaint within 30 days.

Mary B. Templeton, Esq., Deputy General Counsel of Discovery commented, "Discovery Labs is committed to full and prompt disclosure of all material information about our business, financial results and events surrounding our efforts to develop our portfolio of Surfactant Replacement Therapies. We are pleased that our external counsel on this matter, Pepper Hamilton, LP has effectively presented our arguments and that the court has recognized the quality of our disclosures and granted our Motion to Dismiss. We have no information as to whether the plaintiffs plan further filings."

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**For more information, please visit our newly redesigned corporate website at [www.DiscoveryLabs.com](http://www.DiscoveryLabs.com).**

**Company Contact:**

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