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

November 7, 2008
Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On November 4, 2008, Discovery Laboratories, Inc. (the "Company") issued a press release announcing financial results for the quarter ended September 30, 2008. The press release is attached as Exhibit 99.1 hereto.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filings.

Item 8.01. Other Events.

On November 7, 2008, the Company issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted as a Complete Response the Company's formal response to the Approvable Letter dated May 1, 2008, that the FDA issued to the Company in connection with its review of the New Drug Application (NDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established April 17, 2009 as its target action date to complete its review of the Surfaxin NDA. The press release, dated November 7, 2008, is filed as Exhibit 99.2 to this report and is incorporated herein by reference.

On November 10, 2008, the Company held a conference call to discuss the regulatory status of Surfaxin and the Company's financial results for the third quarter ended September 30, 2008. On the call, the Company provided an estimate of the anticipated net cash outflows for the fourth quarter of 2008 of approximately $8.0 million and for the first quarter of 2009 of approximately $7.0 million. Until the FDA has completed its review of the Surfaxin NDA, the Company plans to restrain program development activities to conserve cash resources and to take other actions, including potentially drawing down on its Committed Equity Financing Facilities (CEFFs), aimed at maintaining available cash at a level necessary to fund approximately one year of its projected cash requirements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated November 4, 2008
99.2 Press release dated November 7, 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

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

Date: November 10, 2008

Discovery Labs Reports Third Quarter 2008 Financial Results

Warrington, PA — November 4, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced financial results for the third quarter ended September 30, 2008.

For the quarter ended September 30, 2008, the Company reported a net loss of $10.6 million (or $0.11 per share) on 98.6 million weighted average common shares outstanding compared to a net loss of $9.3 million (or $0.11 per share) on 84.6 million weighted average common shares outstanding for the same period in 2007. For the nine months ended September 30, 2008, the Company reported a net loss of $30.6 million (or $0.31 per share) on 97.3 million weighted average common shares outstanding compared to a net loss of $28.0 million (or $0.35 per share) on 79.5 million weighted average common shares outstanding for the same period in 2007. As of September 30, 2008, the Company had 99.6 million common shares outstanding.

As of September 30, 2008, the Company had cash and marketable securities of $31.5 million, a decrease of $1.9 million from the previous quarter ending June 30, 2008. In the third quarter 2008, cash burn from operating activities, capital expenditures and debt service was $6.2 million, offset by financings pursuant to the Company's Committed Equity Financing Facilities (CEFFs) resulting in aggregate proceeds of $4.3 million from the issuance of 2.8 million shares of common stock. As of September 30, 2008, under the 2008 CEFF, approximately 17.2 million shares are available for issuance for future financings (not to exceed an aggregate of $56.9 million) and, under the 2006 CEFF, approximately 4.5 million shares are available for issuance for future financings (not to exceed an aggregate of $34.3 million). The CEFFs allow the Company, at its discretion, to raise capital (subject to certain conditions, including price and volume limitations) to support its business plans.

Select Company Updates:

- On October 17, 2008, the Company submitted its Complete Response to the May 2008 Approvable Letter issued by the U.S. Food and Drug Administration (FDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The Company believes that the Complete Response adequately addresses the remaining requirements contained in the Approvable Letter that must be satisfied to gain U.S. marketing approval for Surfaxin. Per the FDA guidelines the Company originally anticipated receiving notification by October 31, 2008 regarding the target action date and review classification of the Complete Response for potential approval of Surfaxin. As of the close of business on November 3, the Company had not yet received any such notification from the FDA.

- In September 2008, the Company announced initiation of a Phase 2a clinical trial to investigate the Company's KL-4 surfactant as a treatment for patients with Cystic Fibrosis (CF). The trial is being conducted as an investigator-initiated study under the direction of Dr. Scott H. Donaldson at The University of North Carolina and is funded primarily through a grant provided by the Cystic Fibrosis Foundation.

Third Quarter 2008 Financial Results:

The net loss for the quarter ended September 30, 2008 was $10.6 million compared to $9.3 million for the same period in 2007. Included in the third quarter 2008 and 2007 net loss is a charge of $1.2 million and $1.1 million, respectively, associated with stock-based compensation expense per Financial Accounting Standards No. 123R (FAS 123(R)). The increase in the net loss for the third quarter of 2008 as compared to the third quarter of 2007 is primarily due to (i) beginning in late 2007, investments in U.S. commercial operations to support prelaunch marketing activities in anticipation of the potential approval of Surfaxin in May 2008; and (ii) expenses for the Aerosurf™ development program and the Surfaxin Phase 2 clinical trial in children up to two years of age with Acute Respiratory Failure (ARF).

The primary components of the third quarter 2008 results included:

- research and development expenses of $6.7 million associated with (a) manufacturing development, including quality assurance and analytical activities, to support the production of clinical and potential commercial drug requirements for Surfaxin and the Company's Surfactant Replacement Therapy (SRT) pipeline, (b) activities to obtain data and other information to support the Company's Complete Response to the May 2008 Approvable Letter, (c) development of the Company's capillary aerosolization technology for the delivery of aerosolized SRT, (d) development of new formulations of the Company's SRT technology, (e) internal research and development capabilities (scientific and clinical trial management, regulatory compliance, data management and biostatistics), (f) medical affairs (including medical science liaisons) to provide scientific and medical education support for Surfaxin and the Company's SRT pipeline, and (g) direct expenses for the Aerosurf development program and the Surfaxin ARF Phase 2 clinical trial.

- general and administrative expenses of $3.7 million, including an investment of $1.1 million in the Company's U.S. commercial infrastructure to support the commercial launch of Surfaxin, if approved. In addition, $0.8 million is included in general and administrative expenses, associated with stock-based compensation per FAS123(R).

As of September 30, 2008, the Company had $10.0 million outstanding under its long-term loan with PharmaBio Development Inc. d/b/a Novaquest (a strategic investment group of Quintiles Transnational Corp.). The outstanding principal, together with all accrued and unpaid interest is due and payable on April 30, 2010.

The Company has a secured credit facility with GE Business Financial Services Inc. (GE) to finance capital expenditures through November 30, 2008. As of September 30, 2008, $3.8 million was outstanding under this facility ($2.9 million is classified as a current liability and $0.9 million is classified as a long-term liability) and $154,000 remained available. Also, in September, the Company received $500,000 from the Commonwealth of Pennsylvania Department of Community and Economic Development Machinery and Equipment Loan Fund to finance the purchase of machinery and equipment, of which $444,000 is classified as a long-term liability as of September 30, 2008.

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

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

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made, including, without limitation, the risks that: Discovery Labs' response to the recent Approvable Letter for Surfaxin may not satisfy the FDA; the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that Discovery Labs may file for its products, or may not approve any such applications or may limit marketing of such products to particular indications or impose unanticipated label limitations; changes in the national or international political and regulatory environment may make it more difficult for Discovery Labs to gain FDA or other regulatory approval of its products; Discovery Labs may be unable to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT); Discovery Labs' lengthy and costly research and development programs, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any of its products, including Surfaxin, may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs or its contract manufacturers or materials suppliers may be unable to successfully manufacture adequate supplies of its drug product or drug substances when needed or in amounts sufficient to meet demand; Discovery Labs may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs' drug products with innovative aerosolization technologies; Discovery Labs may be unable to profitably develop and market its products; Discovery Labs may be unable to maintain and protect the patents and licenses related to its SRT technology; other companies may develop competing therapies and/or technologies or health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in securities, product liability and other litigation. The foregoing risks and others are further described in Discovery Labs filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Company Contact:
Lisa Caperelli, Investor Relations
215-488-9413

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

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2008	2007	2008	2007
Revenue from collaborative arrangement and grants	$ 50	$ -	$ 4,600	$ -
Operating expenses: [1]				
Research and development	6,724	6,184	21,394	18,400
General and administrative	3,726	3,147	13,308	9,366
Total expenses	10,450	9,331	34,702	27,766
Operating loss	(10,400)	(9,331)	(30,102)	(27,766)
Other income / (expense)	(239)	(16)	(466)	(275)
Net loss	$ (10,639)	$ (9,347)	$ (30,568)	$ (28,041)
Net loss per common share	$ (0.11)	$ (0.11)	$ (0.31)	$ (0.35)
Weighted average number of common shares outstanding	98,619	84,642	97,324	79,485

(1) Expenses include a charge for stock-based employee compensation in accordance with the provisions of FAS 123(R). For the three and nine months ended September 30, 2008, the charges associated with FAS 123(R) were $1.2 million ($0.4 million in R&D and $0.8 million in G&A) and $3.4 million ($1.1 million in R&D and $2.3 million in G&A), respectively. 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 $0.7 million in G&A) and $3.5 million ($1.1 million in R&D and $2.3 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2008 (unaudited)	December 31, 2007
ASSETS		
Current Assets:		
Cash and marketable securities	$ 31,459	$ 53,007
Receivables, prepaid expenses and other current assets	221	611
Total Current Assets	31,680	53,618
Property and equipment, net	6,324	7,069
Restricted Cash	600	600
Other assets	1,045	1,457
Total Assets	$ 39,649	$ 62,744
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,429	$ 757
Accrued expenses	5,837	7,087
Equipment loan and other liabilities	2,999	2,625
Total Current Liabilities	11,265	10,469
Long-Term Liabilities:		
Loan payable, including accrued interest	10,024	9,633
Equipment loan and other liabilities	2,204	3,861
Total Liabilities	23,493	23,963
Stockholders' Equity	16,156	38,781
Total Liabilities and Stockholders' Equity	$ 39,649	$ 62,744

FDA Establishes Target Action Date of April 17, 2009 for Potential Approval of Discovery Labs' Surfaxin®

Warrington, PA, November 7, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that the U.S. Food and Drug Administration (FDA) has accepted for review Discovery Labs' Complete Response for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has designated the Complete Response as a Class 2 resubmission and has established April 17, 2009 as its target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant marketing approval for Surfaxin.

Discovery Labs will host a conference call on Monday, November 10th at 9:00 AM EST. The call-in number is 866-332-5218.

The Complete Response addressed all of the remaining requirements contained in the May 2008 Approvable Letter that must be satisfied to gain U.S. marketing approval for Surfaxin. Discovery Labs provided the FDA specific data, information and minor clarifying analyses and believes that its Complete Response supports the approval of Surfaxin.

The May 2008 Approvable Letter did not require any additional clinical trials. Prior to receiving the Approvable Letter, Discovery Labs made notable progress towards gaining FDA approval of Surfaxin, including agreeing with the FDA on the content of the Surfaxin package insert and successfully concluding a pre-approval inspection of Discovery Labs' manufacturing operations.

Surfaxin represents the first peptide-containing, synthetic surfactant potentially available for addressing RDS. RDS is a condition in which premature infants are born with an insufficient amount of their own natural surfactant, a substance produced naturally in the lungs and essential for breathing. This condition often requires that infants receive surfactant replacement therapy (currently animal-derived surfactants) along with mechanical ventilation to survive. More than 500,000 infants born each year are at risk for developing RDS in the developed world. In the United States, RDS afflicts approximately 120,000 premature infants annually, of which approximately 80,000 of those infants are treated with the currently-available surfactants.

Conference Call Details

Discovery Labs will hold a conference call on Monday, November 10th at 9:00 AM EST 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=34116&c=DSCO&mediakey=215B789480AB160486E06F003B6A7DC5&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 71465118.

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Discovery Labs' lead product from its SRT pipeline is SURFAXIN® for the prevention of Respiratory Distress Syndrome in premature infants. The U.S. FDA has established April 17, 2009 as its target date to complete its review of this new drug application (NDA) and potentially grant marketing approval for this product. 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.

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