

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

May 5, 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 May 6, 2008, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended March 31, 2008, 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. On May 1, the U.S. Food and Drug Administration (FDA) issued an Approvable Letter for Surfaxin® (lucinactant) for the prevention of RDS in premature infants. The Company also provided updates regarding the restructuring of its collaboration arrangement with Chrysalis Technologies (Chrysalis, a division of Philip Morris USA, Inc.), under which (i) the Company will assume full responsibility, effective July 1, 2008, to further develop the novel capillary aerosolization technology into devices for potential clinical and commercial application, (ii) Chrysalis will pay the Company \$4.5 million to support further device development activities, and (iii) the Company will have a significantly reduced obligation to Chrysalis for the payment of future revenue-based royalties. 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 May 5, 2008, the Company issued a press release providing guidance with respect to the recent FDA Surfaxin Approvable Letter for Surfaxin® (lucinactant) for the prevention of RDS in premature infants. The Company outlined key achievements that occurred prior to May 1, 2008, including (i) the FDA completed a pre-approval inspection of the Company’s manufacturing operations and recently issued an Establishment Inspection Report (EIR) indicating an approval recommendation, and (ii) as of March 2008, the Company’s three Surfaxin process validation batches have successfully attained 12 months stability and continue to demonstrate conformance to established stability specifications. The Company provided guidance about the contents of the Approvable Letter, including its belief that (a) the steps required to file a response may be completed in approximately 6 to 8 weeks, and (b) the response may potentially be designated by the FDA as a Class 1 resubmission with a target review period of 60 days. The overall timeline may be shortened or extended following discussions with the FDA to clarify certain requests in the Approvable Letter. The press release is attached as Exhibit 99.2 to this report and is incorporated herein by reference.

On May 7, 2008, the Company issued a press release announcing that Surfaxin® pre-clinical and clinical data were presented at the *Pediatric Academic Societies Annual Meeting*. In a preclinical study titled “Surfaxin® (lucinactant) Significantly Attenuates Inflammation and Preserves Lung Structural Integrity vs. Animal-derived Surfactants in a RDS Model” (Marla R. Wolfson, *et. al.*) pre-term lambs treated with Surfaxin had better lung function compared with lambs treated with either Survanta®, Curosurf®, or no surfactant replacement. In a second study, “Successful Rapid Extubation to nCPAP Following Surfactant Treatment Does Not Depend on Surfactant Preparation” (Jan Mazela, *et. al.*), a subset of 148 infants from the SELECT Trial (the Company’s pivotal Phase 3 clinical trial for Surfaxin® for the prevention of RDS in premature infants) was analyzed. The objective of the analysis was to determine the rate of successful rapid extubation following surfactant treatment among infants treated with different surfactants. Overall, the trends for the success of extubation at both 7 and 28 days of life and 36 weeks post- conceptual age (PCA) all favored Surfaxin® relative to the comparator surfactants, although these results did not achieve statistical significance. The study concluded that rapid extubation following surfactant treatment can be successfully implemented regardless of the type of the surfactant administered. The press release is attached as Exhibit 99.3 to this report and is incorporated herein by reference.

On May 7, 2008, the Company issued a press release announcing that new data supporting potential unique properties of the Company's novel KL-4 SRT were also presented at the *Pediatric Academic Societies* Annual Meeting. Preclinical studies demonstrate that KL-4 does not induce an immune response known as anaphylaxis and that Surfaxin[®] (lucinactant) displays antimicrobial properties. The press release is attached as Exhibit 99.4 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated May 6, 2008

99.2 Press release dated May5, 2008

99.3 Press release dated May 7, 2008

99.4 Press release dated May 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
Robert J. Capetola, Ph.D.
President and Chief Executive Officer

Date: May 8, 2008



Discovery Labs Reports First Quarter 2008 Financial Results

Warrington, PA — May 6, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced financial results for the first quarter ended March 31, 2008.

For the quarter ended March 31, 2008, the Company reported a net loss of \$9.7 million (or \$0.10 per share) on 96.6 million weighted average common shares outstanding compared to a net loss of \$8.3 million (or \$0.12 per share) on 70.0 million weighted average common shares outstanding for the same period in 2007. As of March 31, 2008, the Company had cash and marketable securities of \$41.5 million and 96.7 million common shares outstanding.

The increase in net loss primarily reflects investments in the Company's operations (i) to prepare for the anticipated approval in the U.S. of SURFAXIN[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, including pre-launch commercialization and medical affairs activities, and (ii) for the further development of Aerosurf[™], aerosolized Surfactant Replacement Therapy (SRT). Discovery Labs' SRT pipeline is based on its novel KL-4 technology. KL-4 is a synthetic peptide that is structurally similar to pulmonary surfactant protein B (SP-B), a substance produced naturally in the lungs and essential for survival and normal respiratory function. Discovery Labs believes that, with its KL-4 technology, SRT has the potential, for the first time, to be developed into a series of respiratory therapies to address patients in the Neonatal Intensive Care Unit (NICU), Pediatric Intensive Care Unit (PICU), Intensive Care Unit (ICU) and other hospital settings.

Select Company Updates:

- On May 1, 2008, the Company received an Approvable Letter from the U.S. Food and Drug Administration (FDA) for SURFAXIN. This official notification sets forth comments that must be addressed to gain U.S. marketing approval for SURFAXIN. The Company believes that the steps required to file a response to the Approvable Letter may be completed in the upcoming 6 to 8 weeks and the response may potentially be designated by the FDA as a Class 1 resubmission with a review target of 60 days, rather than the longer 6 month review target. The overall timeline may be shortened or extended following discussions with the FDA to clarify certain requests in the Approvable Letter. Importantly, the Approvable Letter contains no requirement for additional clinical trials to gain SURFAXIN approval.
 - On March 28, 2008 Discovery Labs and Chrysalis Technologies (Chrysalis, a division of Philip Morris USA, Inc.), agreed to modify their collaboration arrangement. Under the modified collaboration, Discovery Labs will assume full responsibility, effective July 1, 2008, to further develop the capillary aerosolization technology into devices for potential clinical and commercial application. Also under the modified collaboration, Chrysalis will pay to Discovery Labs \$4.5 million to support further device development activities and Discovery Labs will have a significantly reduced obligation to Chrysalis for the payment of future revenue-based royalties. Discovery Labs retains its original exclusive worldwide rights to the capillary aerosolization technology and has received expanded rights in the United States to the capillary aerosolization technology for use with other drugs for respiratory diseases in the hospital setting. The Company is developing its capillary aerosolization technology for use with AEROSURE, the Company's aerosolized SRT delivered through minimally invasive methods, which the Company believes holds the promise to significantly expand the use of surfactants in both neonatal and pediatric critical care medicine.
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John G. Cooper, Executive Vice President and Chief Financial Officer of Discovery Labs, commented, “The Company remains optimistic that SURFAXIN will be approved in 2008. Because of the recent Approvable Letter, we will need to conserve resources and focus our efforts on gaining approval of SURFAXIN. We will also continue to advance the development of AEROSURF. The cash burn for the second quarter is estimated to be between \$9-10 million.”

First Quarter 2008 Operating Results:

The net loss for the quarter ended March 31, 2008 was \$9.7 million compared to \$8.3 million for the same period in 2007. Included in the first quarter 2008 and 2007 net loss is a charge of \$1.1 million and \$0.6 million, respectively, associated with stock-based compensation per Financial Accounting Standards No. 123R (“FAS 123(R)”).

The primary components of the first quarter 2008 results included:

- \$2.0 million of revenue recognized in association with the modification of the collaboration with Chrysalis, in which Chrysalis agreed to pay \$4.5 million to the Company to support further development of the aerosolization capillary technology, of which \$2.0 million became payable within 30 days of execution of the modified arrangement and \$2.5 million will be payable upon completion of technology transfer, which is expected to be completed no later than June 30, 2008.
- manufacturing development expenses (included in research and development expenses) of \$4.3 million, associated with (i) activities for manufacturing, quality assurance and analytical chemistry capabilities to ensure compliance with current good manufacturing practices (cGMP) to support the production of clinical and potential commercial drug requirements for the Company’s SRT pipeline and (ii) activities related to the development and optimization of the initial version of the capillary aerosolization technology system necessary to administer AEROSURF.
- research and development expenses (excluding manufacturing development expenses) of \$2.9 million associated with (a) internal research and development capabilities (scientific and clinical trial management, regulatory compliance, data management and biostatistics) (b) internal medical affairs capabilities (including medical science liaisons) to provide medical and scientific education to support the potential commercial launch of SURFAXIN and the Company’s SRT pipeline, and (c) direct program expenses to advance the Company’s SRT pipeline, primarily (i) preparatory and preclinical activities for anticipated Phase 2 clinical trials for AEROSURF for the prevention and treatment of RDS in premature infants, and (ii) activities related to the ongoing Phase 2 clinical trial to evaluate the use of SURFAXIN in children up to two years of age with Acute Respiratory Failure (ARF).
- general and administrative expenses of \$4.5 million, including \$1.3 million of pre-launch commercialization activities in anticipation of the approval of SURFAXIN related to the establishment of the Company’s own U.S. commercial operations. In addition, of the \$1.1 million total Company expense associated with stock-based employee compensation resulting from FAS123(R), \$0.7 million is included in general and administrative expenses.

Financial Arrangements as of March 31, 2008:

The Company has approximately 5.2 million common shares available for issuance under its Committed Equity Financing Facility (CEFF) for future financings (not to exceed \$35.5 million). Use of the CEFF is subject to certain conditions, including the volume weighted average price of the Company's common stock on each trading day must be at least \$2.00.

The Company has a \$12.5 million secured credit facility with GE Business Financial Services, Inc. to finance capital expenditures. As of March 31, 2008, \$5.2 million was outstanding under this facility (\$2.8 million is classified as a current liability and \$2.4 million is classified as a long-term liability) and \$4.9 million remained available for future use. The ability to draw under the facility expires May 30, 2008, however, the agreement includes a best efforts undertaking to consider a 6-month extension.

The Company had \$9.8 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 interest from July 1, 2006, is due and payable on April 30, 2010.

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 advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

SURFAXIN[®], the Company's 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 may be unable to timely respond, if at all, to the recent approvable letter for Surfaxin; Discovery Labs may not succeed in the FDA or other regulatory agency review process, including that such regulatory authority may not approve the marketing and sale of Surfaxin or any other drug product that Discovery Labs may develop, or such regulatory agency may further delay and/or limit marketing of Surfaxin or any of Discovery Labs' drug products by indication or impose other label limitations; 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); 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 profitably develop and market its products; Discovery Labs' significant, time-consuming and costly research and development activities, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any of its products may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs may be unable to successfully manufacture or provide adequate supplies of drug substances on a timely basis; Discovery Labs may be unable to transfer its manufacturing technology to third-party contract manufacturers or its contract manufacturers or any of its materials suppliers may encounter problems manufacturing drug products or drug substances on a timely basis or manufacture in amounts sufficient to meet demand; 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 be unable to maintain and protect the patents and licenses related to its SRT; 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 Statements of Operations
(in thousands, except per share data)

	Three Months Ended March 31, (unaudited)	
	2008	2007
Revenue	\$ 2,050	\$ --
Operating expenses ⁽¹⁾ :		
Research and development	7,232	5,422
General and administrative	4,505	2,754
Total operating expenses	11,737	8,176
Operating loss	(9,687)	(8,176)
Other income / (expense)	(27)	(134)
Net loss	\$ (9,714)	\$ (8,310)
Net loss per common share	\$ (0.10)	\$ (0.12)
Weighted average number of common shares outstanding	96,649	69,989

(1) Expenses include a charge for stock-based employee compensation in accordance with the provisions of FAS 123(R). For the three months ended March 31, 2008 and 2007, the charges associated with FAS 123(R) were \$1.1 million (\$0.4 million in R&D and \$0.7 million in G&A) and \$0.6 million (\$0.2 million in R&D and \$0.4 million in G&A), respectively.

Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2008	December 31, 2007
	(unaudited)	
<u>ASSETS</u>		
Current Assets:		
Cash and marketable securities	\$ 41,545	\$ 53,007
Prepaid expenses and other current assets	2,442	611
Total Current Assets	43,987	53,618
Property and equipment, net	6,766	7,069
Restricted Cash	600	600
Other assets	1,320	1,457
Total Assets	\$ 52,673	\$ 62,744
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,927	\$ 757
Accrued expenses	4,608	7,087
Equipment loan and other liabilities	2,794	2,625
Total Current Liabilities	9,329	10,469
Long-Term Liabilities:		
Loan payable, including accrued interest	9,781	9,633
Equipment loan and other liabilities	3,265	3,861
Total Liabilities	22,375	23,963
Stockholders' Equity	30,298	38,781
Total Liabilities and Stockholders' Equity	\$ 52,673	\$ 62,744



Discovery Labs Provides Guidance on FDA Approvable Letter for Surfaxin^o for RDS

Warrington, PA — May 5, 2008 —Discovery Laboratories, Inc. (Nasdaq: DSCO) on May 1, 2008 received an Approvable Letter from the U.S. Food and Drug Administration (FDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Discovery Labs' Manufacturing, Quality and Regulatory management have performed an assessment of the remaining conditions set forth in the Approvable Letter that must be satisfied to gain U.S. marketing approval for Surfaxin.

Discovery Labs believes that the steps required to file a response to the Approvable Letter may be completed in the upcoming 6 to 8 weeks and the response may potentially be designated by the FDA as a Class 1 resubmission with a review target of 60 days, rather than the longer 6 month review target. The overall timeline may be shortened or extended following discussions with the FDA to clarify certain requests in the Approvable Letter. Importantly, the Approvable Letter contains no requirement for additional clinical trials to gain Surfaxin approval.

Status of Surfaxin NDA Approval Progress Prior to May 1st Approvable Letter

Key achievements towards gaining FDA approval of Surfaxin include the following:

- On April 30th, Discovery Labs and the FDA agreed to the content of the Surfaxin package insert. Discovery Labs is pleased with the competitive profile of the proposed package insert.
- Discovery Labs has successfully addressed quality and manufacturing issues at its manufacturing operation in Totowa, New Jersey:
 - o In March 2008, the FDA completed a pre-approval inspection (PAI) of Discovery Labs' manufacturing operations and recently issued an Establishment Inspection Report (EIR) indicating an approval recommendation. Discovery Labs' manufacturing operations are prepared for Surfaxin commercial production.
 - o In support of the Surfaxin NDA, Discovery Labs manufactured three Surfaxin process validation batches. As of March 2008, these batches successfully attained 12 months stability and continue to demonstrate conformance to established stability specifications.
- The quality control and quality assurance facilities and operations of Discovery Labs were inspected by the FDA with acceptable results.

May 1st Approvable Letter

Discovery Labs has completed an assessment of the remaining comments set forth in the Approvable Letter that must be addressed to gain U.S. marketing approval for Surfaxin. Discovery Labs firmly believes that this recent Approvable Letter reflects notable progress towards gaining FDA approval for Surfaxin. This Approvable Letter does not include any comments related to Surfaxin analytical chemistry methodology, drug product impurity qualification, or comparability of the current Surfaxin manufacturing process to that used to manufacture drug product employed in the pivotal study.

Discovery Labs' assessment of the Approvable Letter is as follows:

- The release and stability biological activity test for Surfaxin requires further clarification with the FDA. The Approvable Letter included a request to further tighten an acceptance criterion for this biological activity test. Based on data currently available, Discovery Labs believes that it and the FDA can agree upon a final acceptance criterion for the test.
- The Approvable Letter included a request to further tighten acceptance criteria for lipid drug substance impurities. Based on data currently available, Discovery Labs believes that it and the FDA can agree upon final acceptance criteria.
- The Approvable Letter requests further tightening of 2 of the 21 physical and chemical drug product acceptance criteria that were proposed by Discovery Labs in its October 2007 Complete Response. Based on the Surfaxin data set currently available, Discovery Labs can comply with this request.
- The FDA also requested that Discovery Labs submit summary information from certain equipment-related qualification reports for inclusion to the Surfaxin NDA. This information was previously reviewed and found acceptable during the FDA's recent pre-approval inspection of Discovery Labs' manufacturing operations.

On Friday, May 2nd, Discovery Labs contacted the FDA regarding scheduling a meeting to clarify the limited items noted above.

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 related to Discovery Labs' plans to respond to the May 1, 2008 Approvable Letter. Although Discovery Labs believes that it has made significant progress towards gaining approval of Surfaxin, gaining approval of Surfaxin involves ongoing activities, the final results of which could vary materially from Discovery Labs' expectations and results obtained to date. Discovery Labs currently believes that it will succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants within the timeline outlined above; however, these activities are subject to a variety of risks, including but not limited to risks that (i) Discovery Labs may not succeed in scheduling a meeting with the FDA, if at all, within the anticipated timeline outlined in this press release, (ii) Discovery Labs may not succeed in adequately responding to the matters raised in the Approvable Letter, (iii) Discovery Labs' justification of its proposed specifications may not be acceptable to the FDA, and (iv) Discovery Labs, in the process of preparing its response to the Approvable Letter, may identify unforeseen problems that have not yet been discovered. Any failure to provide information required by the FDA or to address the comments raised in the Approvable Letter in our response to the Approvable Letter could result in significant delays or additional requirements and could potentially prevent the approval of Surfaxin or other Discovery Labs' products.

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 designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that, with its proprietary technology, SRT has the potential, for the first time, 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, including, without limitation, the risks that: Discovery Labs may be unable to timely respond, if at all, to the recent approvable letter; Discovery Labs may not succeed in the FDA or other regulatory agency review process, including that such regulatory authority may not approve the marketing and sale of a drug product or may withhold, delay and/or limit marketing of a drug product by indication or impose other label limitations; 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); changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of drug products; Discovery Labs may be unable to profitably develop and market its products; Discovery Labs' significant, time-consuming and costly research and development activities, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any products may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs may be unable to successfully manufacture or provide adequate supplies of drug substances on a timely basis; Discovery Labs may be unable to transfer its manufacturing technology to third-party contract manufacturers or its contract manufacturers or any of its materials suppliers may encounter problems manufacturing drug products or drug substances on a timely basis or manufacture in amounts sufficient to meet demand; 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 be unable to maintain and protect the patents and licenses related to its SRT; 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



Discovery Labs Presents SURFAXIN[®] Data at Pediatric Academic Societies Annual Meeting

Warrington, PA - May 7, 2008 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, announced that SURFAXIN[®] pre-clinical and clinical data were presented at the *Pediatric Academic Societies* Annual Meeting. The *Pediatric Academic Societies* annual meeting is internationally recognized as the largest, most relevant medical meeting dedicated to pediatric research.

The following studies were presented:

SURFAXIN[®] (lucinactant) Significantly Attenuates Inflammation and Preserves Lung Structural Integrity vs. Animal-derived Surfactants in a RDS Model: *Marla R. Wolfson, et al.*

In a preclinical study that utilized a well-established animal model of Respiratory Distress Syndrome (RDS), pre-terms lambs were randomized to receive, by intratracheal instillation, either SURFAXIN[®] (lucinactant), Survanta[®] (beractant), Curosurf[®] (poractant alfa), or no surfactant replacement therapy. Measurements of lung function were performed immediately before and for the four hour period following surfactant administration. Blood and lung samples were collected to measure the presence of inflammatory mediators as well as to examine the structural integrity of the lung. The objective of the study was to assess the effect of SURFAXIN[®] on biomarkers of lung inflammation and lung structure in mechanically ventilated very preterm lambs and to compare these outcomes to those treated with animal-derived surfactants or no surfactant replacement therapy.

The results of the study showed that lambs treated with SURFAXIN[®] had better lung function compared with lambs treated with either Survanta[®], Curosurf[®], or no surfactant replacement as demonstrated by a sustained oxygenation response ($p < 0.05$) and a lower ventilatory pressure requirement ($p < 0.05$). In addition, lambs treated with SURFAXIN[®] had better structural integrity, as assessed by evaluation of lung tissue ($p < 0.05$) and lower levels of lung tissue and blood inflammatory mediators ($p < 0.05$) compared with lambs treated with Survanta[®] or no surfactant replacement therapy.

This study, funded by Discovery Labs, was conducted under the direction of Dr. Marla R. Wolfson, Associate Professor, Departments of Pediatrics and Physiology at Temple University School of Medicine in Philadelphia, PA. The pre-term RDS lamb model was selected because it closely resembles the development, structure, and function of human lungs and is the most relevant system to study the pathophysiology and treatment of RDS.

Successful Rapid Extubation to nCPAP Following Surfactant Treatment Does Not Depend on Surfactant Preparation: *Jan Mazela, et al.*

The current standard treatment for premature infants with RDS typically requires that the infant is intubated to allow mechanical ventilation and surfactant administration. If therapy is successful, extubation occurs when the infant can spontaneously breathe without ventilatory support. Multiple clinical investigations are underway to assess the potential value of rapidly extubating infants with RDS following surfactant administration to determine whether reducing intubation time impacts complications of prematurity.

This study analyzed a subset of 148 infants from the SELECT Trial (Discovery's pivotal Phase 3 clinical trial for SURFAXIN[®] for the prevention of RDS in premature infants). The post-hoc analysis was based on a prospectively defined patient population with pre-specified outcomes measures. The objective of the analysis was to determine the rate of successful rapid extubation following surfactant treatment among infants treated with different surfactants.

Overall, the trends for the success of extubation at both 7 and 28 days of life and 36 weeks post- conceptual age (PCA) all favored SURFAXIN[®] relative to the comparator surfactants, although these results did not achieve statistical significance. The study concluded that rapid extubation following surfactant treatment can be successfully implemented regardless of the type of the surfactant administered.

Robert Segal, M.D., Senior Vice President and Chief Medical Officer of Discovery Labs, commented, "The current treatment approach for babies with RDS requires delivery of surfactants via an endotracheal tube and mechanical ventilation. Mechanical ventilation and supplemental oxygen lead to acute inflammatory responses which may cause bronchopulmonary dysplasia (BPD), also known as chronic lung disease. These data suggest that early intervention with SURFAXIN[®] may mitigate the progression of RDS to BPD. We intend to continue to support research that tests this hypothesis."

About SURFAXIN[®]

SURFAXIN[®], an investigational drug, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. The presentations listed above include information that may be of interest to healthcare practitioners; however, the clinical relevance of this information has not been established.

SURFAXIN[®] is a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant, a substance produced naturally in the lungs and essential for breathing. SURFAXIN[®] is based on the novel KL-4 peptide. KL-4 is a 21-amino acid peptide with structural similarities to pulmonary surfactant protein B (SP-B), the surfactant protein most important for normal respiratory function.

SURFAXIN[®] is also being developed for the prevention and treatment of bronchopulmonary dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS, and the treatment of Acute Respiratory Failure (ARF) in children up to two years of age.

About The Pediatric Academic Societies Annual Meeting

The Pediatric Academic Societies (PAS) consists of the American Pediatric Society, the Society for Pediatric Research and the Ambulatory Pediatric Association. The PAS annual meeting is recognized as the largest, most prestigious meeting dedicated to pediatric research and education in the world and brings together scientists and physicians with expertise in all areas of pediatrics. More than 5,000 pediatric healthcare providers, including approximately 1,100 neonatologists attend this meeting annually.

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 designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that, with its proprietary technology, SRT has the potential, for the first time, 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, including, without limitation, the risks that: Discovery Labs may be unable to timely respond, if at all, to the recent approvable letter; Discovery Labs may not succeed in the FDA or other regulatory agency review process, including that such regulatory authority may not approve the marketing and sale of a drug product or may withhold, delay and/or limit marketing of a drug product by indication or impose other label limitations; 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); changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of drug products; Discovery Labs may be unable to profitably develop and market its products; Discovery Labs' significant, time-consuming and costly research and development activities, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any products may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs may be unable to successfully manufacture or provide adequate supplies of drug substances on a timely basis; Discovery Labs may be unable to transfer its manufacturing technology to third-party contract manufacturers or its contract manufacturers or any of its materials suppliers may encounter problems manufacturing drug products or drug substances on a timely basis or manufacture in amounts sufficient to meet demand; 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 be unable to maintain and protect the patents and licenses related to its SRT; 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.

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Discovery Labs KL-4 Surfactant Technology Displays Antimicrobial Properties and Does Not Induce Immune Response in Preclinical Models

Data Presented at Pediatric Academic Societies Annual Meeting

Warrington, PA - May 7, 2008 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, announced that new data supporting potential unique properties of its novel KL-4 Surfactant Replacement Technology (SRT) were presented at the *Pediatric Academic Societies Annual Meeting*. Preclinical studies were presented demonstrating that KL-4 does not induce an immune response known as anaphylaxis and that SURFAXIN[®] (lucinactant) displays antimicrobial properties. The *Pediatric Academic Societies (PAS) Annual Meeting* is internationally recognized as the largest, most relevant medical meeting dedicated to pediatric research.

One study assessed the potential for KL-4, a 21 amino acid peptide that is structurally similar to pulmonary surfactant protein B (SP-B), to induce an immune response known as anaphylaxis. Anaphylaxis, a potentially life-threatening allergic reaction, can occur in humans after exposure to medications that contain a foreign protein. In this study, a well-established animal model was used to test whether KL-4 would trigger anaphylaxis. The data showed that KL-4 did not induce active or passive anaphylaxis, even when the immune system was potentiated and sensitized.

Another study that was presented at the PAS Annual Meeting investigated the antimicrobial properties of SURFAXIN[®]. In that study, gram-positive and gram-negative bacterial broth was mixed with SURFAXIN[®] and Survanta[®] (beractant), a bovine-derived surfactant, as well as with saline, a negative control, and ciprofloxacin, an antibiotic that served as a positive control. While both SURFAXIN[®] and Survanta[®] suppressed gram-positive bacterial growth, only SURFAXIN[®] suppressed gram-negative bacterial growth.

Dr. Robert Segal, Senior Vice President and Chief Medical Officer of Discovery Labs commented, "Discovery continues to evaluate the attributes of our KL4-based surfactant. The data presented at PAS are exciting in that the studies support a hypothesis that KL4-surfactant potentially has anti-microbial and anti-inflammatory properties. We look forward to continued assessment of these important findings."

About Discovery Labs' Surfactant Technology

Surfactant is produced naturally in the human lungs and is essential for breathing. The uniqueness of Discovery Labs' synthetic peptide-containing SRT products, including SURFAXIN[®] and AEROSURF[™], is based on Discovery Labs' novel KL-4 peptide. KL-4 is a 21-amino acid peptide with structural similarities to pulmonary surfactant protein B (SP-B), the surfactant protein most important for normal respiratory function. KL-4 surfactant technology has the potential to be precisely formulated as a liquid instillate, an aerosolized liquid or a dry powder to address various respiratory diseases affecting premature infants, children and adults.

About SURFAXIN®

SURFAXIN®, an investigational drug, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. The presentations listed above include information that may be of interest to healthcare practitioners; however, the clinical relevance of this information has not been established.

SURFAXIN® is a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant, a substance produced naturally in the lungs and essential for breathing. SURFAXIN® is based on the novel KL-4 peptide. KL-4 is a 21-amino acid peptide with structural similarities to pulmonary surfactant protein B (SP-B), the surfactant protein most important for normal respiratory function.

SURFAXIN® is also being developed for the prevention and treatment of bronchopulmonary dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS and the treatment of Acute Respiratory Failure (ARF) in children up to two years of age.

About The Pediatric Academic Societies Annual Meeting

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