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FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

May 14, 2003  
Date of Report (Date of earliest event reported)

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

|   |                                       |   |
|---|---------------------------------------|---|
| Delaware<br>(State or other jurisdiction<br>of incorporation) | 000-26422<br>(Commission File Number) | 94-3171943<br>(IRS Employer<br>Identification Number) |
|---|---------------------------------------|---|

350 Main Street, Suite 307  
Doylestown, Pennsylvania 18901  
(Address of principal executive offices)

(215) 340-4699  
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Item 7. Financial Statements, Pro Forma Financial Statements and Exhibits

(c) Exhibits:

- 99.1 The 2003 First Quarter Financial Results News Release (as defined in Item 9 below).

Item 9. Regulation FD Disclosure

On May 14, 2003, Discovery Laboratories, Inc., issued a news release announcing financial results for the first quarter ended March 31, 2003, and providing selected updates on the Registrant's progress since the end of fiscal year 2002 (the "2003 First Quarter Financial Results News Release").

The 2003 First Quarter Financial Results News Release is furnished pursuant to Item 9 and in satisfaction of Item 12 pursuant to guidance provided in the Securities and Exchange Commission's Release No. 33-8216 and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing of the Registrant under the Securities Act of 1933. Furthermore, the furnishing of the 2003 First Quarter Financial Results News Release in this Current Report on Form 8-K is not intended to constitute a determination by the Registrant that the information contained therein is material or that the dissemination of such information herein is required by Regulation FD.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Discovery Laboratories, Inc.

By: /s/ Robert J. Capetola

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

Date: May 21, 2003

## Discovery Laboratories Reports First Quarter Financial Results

Doylestown, PA -- May 14, 2003 -- Discovery Laboratories, Inc. (Nasdaq: DSCO), a late-stage specialty biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases, today announced financial results for the first quarter of 2003.

For the quarter ended March 31, 2003, the Company reported a net loss of \$4.5 million, or \$0.14 per share, on approximately 32.9 million weighted average common shares outstanding, compared to a net loss of \$3.37 million, or \$0.13 per share, on approximately 25.8 million weighted average common shares outstanding for the same period in 2002.

The increase in the net loss primarily reflects clinical trial costs incurred for the Company's lead product, Surfaxin(R) (which is currently in three Phase 3 trials and two Phase 2 trials for critical care patients with life threatening respiratory disorders), as well as activities related to the development of the Company's inhalable aerosol surfactant programs to potentially treat a variety of respiratory conditions. The results also include a charge of \$198,000 for pre-launch commercialization activities for Surfaxin for which funding has been provided by a secured, revolving credit facility pursuant to a collaboration arrangement with Quintiles Transnational Corp. ("Quintiles").

The increase in the weighted average number of shares outstanding is primarily due to approximately 822,000 common shares issued in connection with the March 2002 expansion of the strategic alliance with Laboratorios del Dr. Esteve ("Esteve") and approximately 6.4 million common shares issued to selected institutional and accredited investors in a private offering in November 2002. As of March 31, 2003 and March 31, 2002, there were approximately 32.9 million and 26.4 million common shares issued and outstanding, respectively.

As of March 31, 2003, the Company had cash and investments of approximately \$14.2 million. In addition the Company has a secured revolving credit facility of \$8.5 million to \$10.0 million with Quintiles. The Company may use this credit facility for general working capital purposes but is obligated to use a majority of the funds borrowed under this facility for pre-launch marketing of Surfaxin. This credit facility is available for use through December 10, 2004, and monies become available in three tranches upon satisfying certain conditions. We have satisfied the conditions for availability of the first two tranches and as of March 31, 2003, \$5.7 million was available for borrowing and \$1.65 million was outstanding under the credit facility. The Company has a capital lease financing arrangement with the Life Science and Technology Finance Division of General Electric Capital Corporation that provides, subject to certain conditions, for up to \$1.0 million in financing for capital purchases. As of March 31, 2003, the Company has used approximately \$475,000 of this financing arrangement. Our currently available financial resources will be adequate to satisfy our capital needs into the second quarter of 2004.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery stated, "Surfactant Replacement Therapies have the potential to treat several respiratory diseases or to prevent

respiratory conditions from becoming severe, even life-threatening, events. We are the only company with a humanized surfactant technology platform that can be developed into a pipeline of Surfactant Replacement Therapies tailored for specific respiratory conditions. Our lead product, Surfaxin (a liquid instillate), is in three Phase 3 and two Phase 2 clinical trials for critical care patients suffering from various Respiratory Distress Syndromes. Discovery has recently expanded its product pipeline to include inhalable aerosol surfactant formulations and we are positioned to enter Phase 1b/2a clinical trials for asthma and Acute Lung Injury. We remain focused on executing the critical operational and clinical milestones necessary to build a meaningful specialty biopharmaceutical company that has the potential to bring groundbreaking respiratory therapies to patients with limited or no effective treatments currently available."

Selected updates on the Company's progress in the first quarter:

- o Pivotal, Multinational Landmark Phase 3 Clinical Trial for Respiratory Distress Syndrome (RDS) in Premature Infants - This trial is intended to provide the basis for New Drug Applications with the FDA and other worldwide regulatory authorities. The Company's existing base of 50 qualified clinical sites are enrolling and treating patients in a manner that is consistent with the expectation that this trial will be completed and data announced early in the fourth quarter of 2003.

- o Supportive Phase 3 RDS Trial - The Company is currently conducting a supportive multinational Phase 3 trial (referred to as the KL4-IRDS-02 Trial) to demonstrate the safety and non-inferiority of Surfaxin compared to Curosurf(R), an approved porcine lung extract, for the treatment of Respiratory Distress Syndrome in premature infants. The Company is evaluating whether to conclude this trial early to conserve financial resources and reallocate clinical resources to its pivotal Phase 3 trial.
  
- o Part B, Phase 2 Clinical Trial for Acute Respiratory Distress Syndrome in Adults (ARDS) - Enrollment for this trial is expected to be completed in the fourth quarter of 2003. Akorn, Inc., the Company's contract manufacturer for Surfaxin for this trial, informed us previously that certain operating difficulties experienced in one of its production rooms, primarily used for the filling of sterile pharmaceuticals, had been rectified and that the room had been returned to operational status. Manufacturing activities for Surfaxin for our ARDS trial recommenced in March 2003 and certain filling-related processes, solely related to Akorn's sterile filling room, needed additional attention. These issues have been addressed to the satisfaction of the Company's manufacturing personnel and the Company believes that Akorn will be on schedule to recommence Surfaxin manufacture for this trial by the end of May 2003.
  
- o Surfaxin Manufacturing - In light of the late stage development status of Surfaxin, the ongoing implementation of the Company's commercialization strategy, and in preparation for its inhalable aerosol clinical programs, the Company is evaluating several additional contract manufacturing sites and investing in manufacturing scale-up and enhancements, including equipment. The Company expects to select its second

contract manufacturer in the second quarter of 2003 and have this additional manufacturing capability operational by the fourth quarter of 2003.

- o Inhalable Aerosol Surfactant Formulations - The Company aerosolized its humanized lung surfactant as an inhalable liquid formulation that retained the essential pharmacological properties of a functioning surfactant (i.e., the surface-tension lowering ability necessary to restore lung function and keep airways open and expanded) and could achieve delivery rates necessary for therapeutic dosing in an appropriate time period. The Company believes that Surfactant Replacement Therapy for respiratory medicine has now evolved to where aerosol formulations of engineered lung surfactant have the potential to be developed to treat a broad range of respiratory diseases.
- o SARS and Surfactant Replacement Therapies - On Wednesday, May 7, 2003, Dr. Robert J. Capetola testified before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations regarding the possible application of the Company's Surfactant Replacement Therapy programs to address Severe Acute Respiratory Syndrome (SARS). SARS is an acute respiratory illness in which patients have difficulty breathing. Dr. Capetola informed the Committee that Surfactant Replacement Therapy has the potential to play an important role in addressing the SARS crisis because it is intended to maintain or restore proper lung function. If the necessary activities, parties and adequate resources could be properly organized, Surfactant Replacement Therapy could be evaluated for the most severe SARS patients on mechanical ventilation as early as mid-to-late-summer of 2003, and inhalable surfactant aerosol formulations could be evaluated for maintaining lung function in SARS patients by fall of 2003.
- o Anti-Inflammatory Properties - Research at the University of Pennsylvania Department of Medicine, Pulmonary, Allergy and Critical Care Division established that Discovery's humanized lung surfactant, including Surfaxin, exhibits significant anti-inflammatory properties in the lungs. Many respiratory diseases, such as Acute Respiratory Distress Syndrome, Acute Lung Injury, asthma, and chronic obstructive pulmonary disease (COPD), are associated with an inflammatory event and degradation of natural lung surfactant.

#### About Discovery Laboratories

Discovery Laboratories, Inc. is a specialty biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes, Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disease (COPD), and upper airway disorders. Discovery's surfactant technology produces an engineered version of natural human lung surfactant that is designed to precisely mimic the essential properties of human lung surfactant. Discovery believes that through its surfactant technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for hospitalized and ambulatory patients. Surfaxin, Discovery's lead product, is in three Phase 3 and two Phase 2 clinical trials for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. Discovery's first aerosol surfactant product is positioned to enter clinical trials for hospital patients with severe asthma

or acute lung injury. Discovery has a commercialization alliance with Quintiles Transnational Corp. and a strategic alliance with Laboratorios del Dr. Esteve S.A.

Interested parties can receive corporate updates by sending their email addresses to [dsc0@focuspartners.com](mailto:dsc0@focuspartners.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 the Company's product development, events conditioned on stockholder or other approval, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. The forward-looking statements contained in this release 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 the company's actual results and could cause results to differ from those contained in the forward-looking statements contained herein are the risk that financial conditions may change, risks relating to the progress of the company's research and development, the risk that the Company will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies), risks relating to the progress of the Company's research and development, risks relating to the lack of sufficient drug product for completion of any of the Company's clinical studies, and risks relating to the development of competing therapies and/or technologies by other companies. Those associated 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-KSB, 8-K, 10-QSB and 10-Q, and amendments thereto.

(tables to follow)

Discovery Laboratories, Inc.

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

|  | Three months ended<br>March 31, |            |
|--|---------------------------------|------------|
|  | 2003                            | 2002       |
|  | -----                           | -----      |
| Revenues from collaborative agreements               | \$ 393                          | \$ 237     |
| Operating expenses                                   |                                 |            |
| Research and Development                             | 3,844                           | 2,605      |
| General and Administrative                           | 1,167                           | 1,132      |
|  | -----                           | -----      |
| Total Expenses                                       | 5,011                           | 3,737      |
| Operating loss                                       | (4,618)                         | (3,500)    |
| Other income and expense (net)                       | 113                             | 130        |
|  | -----                           | -----      |
| Net loss   | \$ (4,505)                      | \$ (3,370) |
|  | =====                           | =====      |
| Net loss per common share                            | \$ (0.14)                       | \$ (0.13)  |
| Weighted average number of common shares outstanding | 32,857                          | 25,834     |

Condensed Consolidated Balance Sheets  
(in thousands)

|   | March 31,<br>2003 | December 31,<br>2002 |
|---|-------------------|----------------------|
|   | ----              | ----                 |
|   | (unaudited)       |                      |
| ASSETS  |                   |                      |
| Current assets:   |                   |                      |
| Cash, cash equivalents and available-for-sale marketable securities | \$ 14,170         | \$ 19,192            |
| Prepaid expenses and other current assets                           | 259               | 325                  |
|   | -----             | -----                |
| Total current assets  | 14,429            | 19,517               |
| Property and equipment, net of depreciation                         | 1,409             | 1,231                |
| Other assets  | 302               | 314                  |
|   | -----             | -----                |
| Total assets  | \$ 16,140         | \$ 21,062            |
|   | =====             | =====                |
| LIABILITIES AND STOCKHOLDERS' EQUITY                                |                   |                      |
| Total current liabilities   | \$ 2,805          | \$ 3,202             |
| Deferred revenue  | 1,213             | 1,393                |
| Credit facility with corporate partner                              | 1,648             | 1,450                |
| Capitalized lease   | 348               | 256                  |
|   | -----             | -----                |
| Total liabilities   | 6,014             | 6,301                |
|   | -----             | -----                |
| Stockholders' equity  | 10,126            | 14,761               |
|   | -----             | -----                |
| Total liabilities and stockholders' equity                          | \$ 16,140         | \$ 21,062            |
|   | =====             | =====                |