
FORM 8-K

CURRENT REPORT

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

August 5, 2004
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) |
|---------------------------------------------------------------|---------------------------------------|-------------------------------------------------------|

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 2004 Second Quarter Financial Results News Release (as defined in Item 12 below).

Item 12. Results of Operations and Financial Condition

On August 5, 2004, Discovery Laboratories, Inc. (the "Registrant"), issued a news release announcing financial results for the quarter ended June 30, 2004, and providing selected updates on the Registrant's progress since the end of its first fiscal quarter in 2004 (the "2004 Second Quarter Financial Results News Release"). The full text of the press release is set forth in Exhibit 99.1 hereto. The information in this Form 8-K and the exhibit 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.

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: August 5, 2004

[LOGO OF DISCOVERY LABORATORIES]

DISCOVERY LABORATORIES REPORTS SECOND QUARTER 2004 FINANCIAL RESULTS

DOYLESTOWN, PA -- AUGUST 5, 2004 -- DISCOVERY LABORATORIES, INC. (NASDAQ: DSCO), today announced financial results for the second quarter of 2004. The Company will host a conference call today at 10:30 AM EDT. The call in number is 800-665-0669.

For the quarter ended June 30, 2004, the Company reported a net loss of \$8.9 million, or \$0.19 per share, on approximately 46.7 million weighted average common shares outstanding, compared to a net loss of \$4.8 million, or \$0.14 per share, on approximately 33.5 million weighted average common shares outstanding for the same period in 2003. For the six months ended June 30, 2004, the Company reported a net loss of \$17.8 million, or \$0.39 per share, on approximately 45.0 million weighted average common shares outstanding, compared to a net loss of \$9.4 million, or \$0.28 per share, on approximately 33.2 million weighted average common shares outstanding for the same six-month period in 2003.

As of June 30, 2004, the Company had cash and marketable securities of approximately \$41.3 million, an increase of approximately \$17.7 million from the previous quarter. Included in this change in cash and marketable securities are net proceeds of \$22.8 million from an underwritten public offering of 2,200,000 shares of common stock in April 2004. Excluding this financing, cash decreased from the previous quarter by \$5.1 million due to the use of approximately \$8.9 million for operating and investing activities offset by \$2.1 million of net proceeds from the use of existing credit and capital lease facilities and \$2.0 million received from the exercise of certain options and warrants. In addition, as of June 30, 2004, approximately \$1.7 million was outstanding under the Company's \$4 million capital lease financing arrangement with General Electric Capital Corporation and approximately \$4.8 million was outstanding under the Company's secured revolving credit facility of \$8.5 to \$10 million with PharmaBio Development Inc.

Additionally, in July 2004, the Company entered into a Committed Equity Financing Facility Agreement (CEFF) with Kingsbridge Capital Limited (Kingsbridge) in which Kingsbridge committed to finance up to \$75 million of capital to support the Company's future growth. Subject to certain terms and conditions, the CEFF allows the Company to raise capital as required, at the time, price and in amounts deemed suitable to the Company, during a three-year period once a registration statement is filed by the Company and declared effective by the Securities and Exchange Commission.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "Discovery now is focusing on preparing for the commercialization of Surfaxin(R) for Respiratory Distress Syndrome (RDS), if approved. We are also advancing our franchise of Surfactant Replacement Therapies (SRT) that are intended to address the range of respiratory disorders treated in the Neonatal Intensive Care Unit (NICU), critical care and hospital settings.

We have made great progress in our Phase 2 clinical program for Acute Respiratory Distress Syndrome (ARDS) in adults. We remain confident that our SRT lavage, or lung wash, technique is the most scientifically sound approach to the treatment of ARDS. During the second half of this year, we will focus also on advancing our aerosol SRT clinical programs. We are extremely enthusiastic that

non-invasive aerosol SRT will provide significant therapeutic benefits to both children and adults suffering from respiratory diseases. Now, with potential financial resources of approximately \$120 million, we can focus on executing our Surfaxin RDS commercialization strategy and advancing our broad SRT pipeline," continued Dr. Capetola.

The net loss increased by \$4.0 million to \$8.9 million, and \$8.4 million to \$17.8 million, respectively, for the three and six months ended June 30, 2004, as compared to the same periods last year, primarily due to:

- (i) manufacturing activities (which are included in research and development), of which \$1.9 million and \$3.7 million, respectively, was incurred for the three and six months ended June 30, 2004 to support the production of clinical and commercial drug supply of the Company's Surfactant Replacement Therapies (including Surfaxin) in conformance with current Good Manufacturing Practices (cGMPs). For the comparable periods last year, no such costs were incurred;
- (ii) pre-launch commercialization activities for Surfaxin (which are

included in general and administrative expenses) of \$1.1 million and \$2.0 million, respectively, for the three and six months ended June 30, 2004. The majority of such costs were financed through the Company's secured, revolving credit facility with PharmaBio;

- (iii) non-cash compensation and non-recurring charges (which are included in general and administrative expenses) totaling approximately \$700,000 in general and administrative expenses in the second quarter primarily consisting of a milestone payment to Johnson & Johnson, Inc., payable upon submission of the Company's New Drug Application (NDA) related to the Company's Surfaxin sublicense, a listing fee paid to NASDAQ upon acceptance of the Company's application to trade its common stock on the National Market (previously listed on the NASDAQ SmallCap Market), and non-cash charges related to stock options granted to employees and consultants under our Amended and Restated 1998 Stock Option Plan; and
- (iv) research and development activities related to the advancement of the Company's SRT pipeline, including its lead product Surfaxin.

Selected updates on the Company's programs and progress:

SRT IN THE NICU

- o SURFAXIN FOR RESPIRATORY DISTRESS SYNDROME (RDS) IN PREMATURE INFANTS
On June 15, 2004, the United States Food and Drug Administration (FDA) accepted the Company's NDA filing for Surfaxin for the prevention of RDS in premature infants. The FDA has established a target date of February 13, 2005 for completion of review of the Surfaxin NDA.

The Company is also preparing a Marketing Authorization Application (MAA) to be filed with the European Medicines Evaluation Agency (EMA) in the second half of 2004 for Surfaxin for the prevention and treatment of RDS. In June, the Committee for Orphan Medicinal Products (COMP) of the EMA adopted a positive opinion recommending the granting of orphan medicinal product designation for Surfaxin for the prevention and treatment of RDS. In making its assessment the COMP concluded that although satisfactory methods of prevention and treatment of RDS have been authorized in Europe, justifications have been provided that Surfaxin may be of significant benefit to those at risk of developing or affected by the condition.

Effective June 22, 2004, Quintiles completed a written assessment and report of the Company's Surfaxin NDA. Based on the quality of the clinical data and documentation comprising the NDA, Quintiles determined that such NDA was deemed "approvable" by the FDA. This determination allows the Company to access the remaining amounts available under the secured revolving credit facility of \$8.5 to \$10 million with PharmaBio Development Inc.

o AEROSOLIZED SURFACTANT IN COMBINATION WITH NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE (NCPAP) FOR NEONATAL PULMONARY DISORDERS

To further the Company's commitment to potentially address the range of neonatal pulmonary disorders in the NICU, we are preparing a Phase 2 clinical trial using our aerosolized SRT in combination with nCPAP. We believe that this approach represents a non-invasive surfactant-based therapy for premature infants and has the potential to reduce the need for and complications from mechanical ventilation, including lowering the risk of infection. We anticipate initiating such trial in the United States in late 2004.

SRT FOR CRITICAL CARE AND HOSPITAL

o SURFACTANT REPLACEMENT THERAPY FOR ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS) IN ADULTS

The Company's manufacturing capability, through its arrangements with Laureate Pharma, L.P., have now provided adequate Surfaxin ARDS product to supply all participating clinical sites in order to complete Part B of the Phase 2 study. We expect to complete this trial in the fourth quarter of 2004.

o DSC-104 FOR ASTHMA

The Company convened its Asthma Scientific Advisory Board, comprised of leading international experts in asthma, to establish a Phase 2 clinical trial strategy for patients with moderate to severe asthma. The Company anticipates initiating this trial in the fourth quarter of 2004.

ABOUT DISCOVERY LABORATORIES

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases. Surfactants are compositions produced naturally in the lungs and essential for breathing. Discovery's technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human lung surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery has filed a New Drug Application with the FDA for clearance to market Surfaxin, the Company's lead product, for the prevention of Respiratory Distress Syndrome in premature infants. Discovery is currently conducting a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, and Phase 3 and Phase 2 clinical trials for Meconium Aspiration Syndrome in full-term infants. With aerosolized surfactant formulations, Discovery is preparing to initiate a Phase 2 trial for asthma (development name DSC-104) and a Phase 2 trial for Respiratory Dysfunction in premature infants.

More information about Discovery is available on the Company's Web site at 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 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 Private 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), risk of delay in the Company's preparation and filing of applications for regulatory approval, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by the Company, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by the Company for any such drug product, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with adequate supplies of drug substance and drug products for completion of any of the Company's clinical studies, other risks relating to the lack of adequate supplies of drug substance and 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. 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 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.

COMPANY CONTACTS:

John G. Cooper, EVP and CFO
Kori Beer, IR & Communications
215-340-4699

DISCOVERY LABORATORIES, INC.

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(in thousands, except per share data)
(unaudited)

| | THREE MONTHS ENDED JUNE 30, 2004 | | SIX MONTHS ENDED JUNE 30, 2004 | |
|------------------------------------------------------|-------------------------------------|------------|-----------------------------------|------------|
| | 2004 | 2003 | 2004 | 2003 |
| Revenues from collaborative agreements | \$ 697 | \$ 263 | \$ 839 | \$ 657 |
| Operating expenses: | | | | |
| Research and Development | 6,123 | 4,011 | 12,833 | 7,855 |
| General and Administrative | 3,425 | 1,137 | 5,706 | 2,304 |
| Total expenses | 9,548 | 5,148 | 18,539 | 10,159 |
| Operating loss | (8,851) | (4,885) | (17,700) | (9,502) |
| Other income and expense | (46) | 36 | (69) | 148 |
| Net loss | \$ (8,897) | \$ (4,849) | \$ (17,769) | \$ (9,354) |
| Net loss per common share | \$ (0.19) | \$ (0.14) | \$ (0.39) | \$ (0.28) |
| Weighted average number of common shares outstanding | 46,683 | 33,487 | 45,003 | 33,172 |

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

| | JUNE 30, 2004 | DECEMBER 31, 2003 |
|---------------------------------------------------|------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash, cash equivalents, and marketable securities | \$ 41,309 | \$ 29,422 |
| Prepaid expenses and other current assets | 1,271 | 668 |
| Total current assets | 42,580 | 30,090 |
| Property and equipment, net of depreciation | 2,922 | 2,414 |
| Other assets | 210 | 211 |
| Total assets | \$ 45,712 | \$ 32,715 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Credit facility with corporate partner | \$ 4,811 | \$ 2,436 |
| Other current liabilities | 5,211 | 4,593 |
| Total current liabilities | 10,022 | 7,029 |
| Deferred revenue | 403 | 672 |
| Capitalized lease | 1,187 | 711 |
| Total liabilities | 11,612 | 8,412 |
| Stockholders' equity | 34,100 | 24,303 |

Total liabilities and stockholders' equity

\$ 45,712
=====

\$ 32,715
=====