

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 8-K

CURRENT REPORT

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

August 12, 2003  
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)
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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 5. Other Events and Regulation FD Disclosure

On August 12, 2003, Discovery Laboratories, Inc. (the "Company"), issued a news release announcing financial results for the second quarter ended June 30, 2003, and providing selected updates on the Registrant's progress since the end of the first quarter (the "2003 Second Quarter Financial Results and Trial Update News Release"). Such updates included the transferring of the Company's Surfaxin(R) manufacturing capabilities to a new contract facility in connection with implementing the initial phase of its long-term manufacturing strategy. No delay is expected regarding the planned completion of the Company's ongoing pivotal Phase 3 clinical trial for Respiratory Distress Syndrome (RDS) in premature infants, however, as a result, the timeline for the completion of the Company's Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults is being adjusted from the fourth quarter of 2003 to the second quarter of 2004.

In order to implement its long-term manufacturing strategy, the Company is currently negotiating the final terms and conditions of an agreement pursuant to which Laureate Pharma, L.P. ("Laureate Pharma"), would become the Company's contract manufacturer for Surfaxin(R). Until the execution of said agreement, Laureate Pharma is not obligated to manufacture any drug products for the Company. There can be no assurance that the Company and Laureate Pharma will ultimately execute such agreement nor that such agreement ultimately will be on terms favorable to the Company. If the agreement is not executed, the Company may pursue alternative manufacturing arrangements, which may delay or impair its ability to obtain regulatory approval for its products or be available only on terms that are not favorable to the Company.

The full text of the 2003 Second Quarter Financial Results and Trial Update News Release is set forth in Exhibit 99.1 hereto and except for the reference to the Company's website is incorporated in this Report as if fully set forth herein.

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

(c) Exhibits:

99.1 The 2003 Second Quarter Financial Results and Trial Update News Release (as defined in Item 5 above).

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: August 12, 2003

[LOGO]  
DISCOVERY LABORATORIES, INC.

## Discovery Laboratories Reports Second Quarter Financial Results

Implements Initial Phase of Long-Term Manufacturing Strategy

ARDS Phase 2 Completion Date Adjusted to Second Quarter 2004

Doylestown, PA -- August 12, 2003 -- Discovery Laboratories, Inc. (Nasdaq: DSCO), a late-stage biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases, today announced financial results for the second quarter ended June 30, 2003. The Company also announced that it is transferring its Surfaxin manufacturing capabilities to a new contract facility in connection with implementing the initial phase of its long-term manufacturing strategy. No delay is expected regarding the planned completion of the Company's ongoing pivotal Phase 3 clinical trial for Respiratory Distress Syndrome in premature infants, however, the timeline for the completion of the Company's Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults is being adjusted from the fourth quarter of 2003 to the second quarter of 2004.

For the second quarter ended June 30, 2003, the Company reported a net loss of \$4.85 million, or \$0.14 per share, on approximately 33.5 million weighted average common shares outstanding, compared to a net loss of \$4.29 million, or \$0.16 per share, on approximately 26.4 million weighted average common shares outstanding for the same period in 2002. For the six months ended June 30, 2003, the Company reported a net loss of \$9.35 million, or \$0.28 per share on approximately 33.2 million weighted average common shares outstanding, compared to a net loss of \$7.66 million, or \$0.29 per share on approximately 26.1 million weighted average common shares outstanding for the same period in 2002.

As of June 30, 2003, the Company had cash and investments of approximately \$35.5 million. In addition, during June and July of 2003, the Company's Common Stock attained certain exchange-related price performance thresholds permitting the Company to redeem (and thereby effectively compel the exercise of) three of its outstanding classes of warrants to purchase Common Stock. The Class I, Class F and Class C warrants were previously issued by the Company in connection with certain private placement financings that occurred in November 2002, October 2001 and April 1999, respectively. The maximum number of shares of Common Stock issuable upon exercise of the three classes of warrants at the time of redemption was approximately 3.6 million. As of August 12, 2003, 2.8 million of the total 3.6 million warrants have been exercised with approximately 2.6 million shares of Common Stock issued and aggregate cash proceeds of \$5.7 million received by the Company.

Robert J. Capetola, Ph.D., President and CEO of the Company, stated, "We believe that our humanized surfactant technology is the only one capable of producing high quality surfactants with the potential to address a broad range of life-threatening respiratory disorders and large pharmaceutical markets. The positive clinical data from our recently completed Phase 3 supportive trial of Surfaxin for Respiratory Distress Syndrome in premature infants, the encouraging results of Part A of our Phase 2 trial of Surfaxin for Acute Respiratory Distress Syndrome in adults, and the development of our engineered surfactant as an inhalable aerosol all provide compelling validation of our surfactant technology platform. In June 2003, the financial community responded positively to these results and created the opportunity for us to significantly strengthen our financial position by completing a private financing of approximately \$27.5 million."

"For the remainder of this year, our primary focus is on driving our late-stage clinical programs and implementing our long-term business strategy. The completion of our pivotal Phase 3 trial for Surfaxin for Respiratory Distress Syndrome in premature infants is our number one priority and the announcement of data remains on schedule for the fourth quarter of this year. Additionally, Part B of our Phase 2 clinical trial for Surfaxin in Acute Respiratory Distress Syndrome in adults, a disease for which no approved treatment currently exists, is ongoing and enrollment continues. In line with our continued confidence in these lead programs, we are implementing the first stages of an improved long-term manufacturing program and we are increasing our Surfaxin pre-launch commercialization activities with our collaborative partners," further commented Dr. Capetola.

The Company is implementing its long-term manufacturing strategy through the recent selection of Laureate Pharma, L.P., to become its current contract manufacturer. Laureate Pharma will replace the Company's previous contract

manufacturer, Akorn, Inc. who has been experiencing operational and financial difficulties. Laureate Pharma has cGMP-compliant manufacturing facilities in Princeton and Totowa, New Jersey and a successful history of producing sterile pharmaceutical and biopharmaceutical products. In connection with the first phase of the implementation plan with Laureate Pharma, the Company has transferred its existing manufacturing equipment from Akorn. Plans include having Laureate Pharma produce clinical material by the fourth quarter of 2003. This arrangement also encompasses plans for manufacturing scale-up and enhancements, including additional equipment to support commercial-scale RDS requirements and ARDS late-stage, clinical-scale production of Surfaxin.

Selected updates on the Company's programs and progress since the end of the first quarter:

- o Phase 3 Clinical Trials for Respiratory Distress Syndrome (RDS) in Premature Infants - The Company's landmark, pivotal, multinational Phase 3 clinical trial for Respiratory Distress Syndrome (RDS) is ongoing with enrollment nearing completion and the expectation that this trial will be completed with data announced early in the fourth quarter of 2003. This trial is intended to provide the basis for New Drug Applications with the FDA and other worldwide regulatory authorities. The establishment of the Laureate Pharma manufacturing capability of Surfaxin is not expected to delay the completion of the RDS Phase 3 trial.

In June 2003, the Company announced positive results of key endpoints of its supportive Phase 3 multinational clinical trial of Surfaxin for RDS. This supportive trial was designed as a non-

inferiority study comparing Discovery's humanized Surfaxin to Curosurf(R), an approved pig-lung extract. Preliminary analysis of the trial's primary endpoint showed Surfaxin to be statistically equivalent to Curosurf, with a relative difference in favor of Surfaxin. Curosurf is considered by many of the world's leading neonatologists to be the best surfactant currently approved. Further analyses of secondary endpoints and safety parameters are being completed, and a detailed presentation of the results of the trial will be made at the European Society for Pediatric Research (ESPR) meeting in Bilbao, Spain on September 27 - 30, 2003.

- o Part B, Phase 2 Clinical Trial for Acute Respiratory Distress Syndrome (ARDS) in Adults - Akorn has been the Company's contract manufacturer for Surfaxin for this trial. Although Akorn's operating difficulties have been unrelated to the Company's proprietary Surfaxin manufacturing process and equipment, Akorn's continuing difficulties with its sterile production facilities has caused it to be unable to return to operational status on a consistent basis. The Company believes that it can no longer rely on Akorn as a viable source of Surfaxin clinical supply for the remainder of this trial or a potential Phase 3 trial. Although the Company plans to have Surfaxin clinical material available from its Laureate Pharma manufacturing program in the fourth quarter of 2003, these events have extended the anticipated completion of this trial from the fourth quarter of 2003 to the second quarter of 2004.
- o Private Placement Financing - In June 2003, the Company completed the sale of securities in a private placement to selected institutional and accredited investors for gross proceeds of approximately \$27.5 million. Under the terms of the financing, the Company sold approximately 5.0 million newly issued shares of Common Stock at a purchase price of \$5.50 per share and warrants exercisable for approximately 1.0 million shares of common stock with an exercise price of \$6.875 per share.

Additional key financial results:

- o The change in the net loss for the quarter and six months ended June 30, 2003, primarily reflects increased R&D expenses for clinical trial costs for the Company's lead product, Surfaxin, currently in Phase 3 and Phase 2 clinical trials for critical care patients with various 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.
- o The change in net loss also includes decreased revenues related to (i) the conclusion of work associated with the Company's Small Business Innovative Research (SBIR) grant for research in Acute Lung Injury/Acute Respiratory Distress Syndrome (ALI/ARDS) in adults and its Orphan Products Development grant to develop Surfaxin for Meconium Aspiration Syndrome (MAS) in full-term infants; and (ii) the extension of the amortization period and related revenue recognition of the funding previously provided to the Company in connection with its strategic alliance with Laboratorios del Dr. Esteve, S.A., which now reflects the planned fourth quarter 2003 completion of the Company's Phase 3 pivotal clinical trial for Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants.

- o As of June 30, 2003 and June 30, 2002, there were approximately 38.5 million and 26.4 million common shares issued and outstanding, respectively. The increase in the number of shares outstanding is primarily due to approximately 6.4 million and approximately 5.0 million common shares issued in private offerings to selected institutional and accredited investors in November 2002 and June 2003, respectively.
- o The Company has a secured revolving credit facility of \$8.5 million to \$10.0 million with PharmaBio Development Inc., a subsidiary of Quintiles Transnational Corp., that is available for use through December 10, 2004. As of June 30, 2003, \$5.7 million was available for borrowing and \$1.8 million was outstanding under the credit facility. The Company also 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 June 30, 2003, the Company has used approximately \$475,000 of this financing arrangement.

#### About Discovery Laboratories

Discovery Laboratories, Inc. is a late-stage 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 Phase 3 and Phase 2 clinical trials for critical care patients with various 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.

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), risks relating to the progress of the Company's research and development, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with sufficient amounts of drug products for completion of any of the Company's clinical studies, other 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-Q and 10-QSB, and amendments thereto.

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(tables to follow)

Discovery Laboratories, Inc.  
Condensed Consolidated Statements of Operations  
(in thousands, except per share data)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
	-----		-----	
Revenues from collaborative agreements	\$ 263	\$ 783	\$ 657	\$ 1,020
Operating expenses				
Research and Development	4,011	3,721	7,855	6,326
General and Administrative	1,137	1,538	2,304	2,670
	-----		-----	
Total expenses	5,148	5,259	10,159	8,996
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Operating loss	(4,885)	(4,476)	(9,502)	(7,976)
Other income and expense	36	189	148	319
	-----		-----	
Net loss	\$ (4,849)	\$ (4,287)	\$ (9,354)	\$ (7,657)
	=====		=====	
Net loss per common share	\$ (0.14)	\$ (0.16)	\$ (0.28)	\$ (0.29)
Weighted average number of common shares outstanding	33,487	26,394	33,172	26,114

Condensed Consolidated Balance Sheets  
(in thousands)

	June 30, 2003	December 31, 2002
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	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash, cash equivalents and available-for-sale marketable securities	\$35,513	\$19,190
Prepaid expenses and other current assets	473	327
	-----	
Total current assets	35,986	19,517
Property and equipment, net of depreciation	1,433	1,231
Other assets	289	314
	-----	
Total assets	\$37,708	\$21,062
	=====	
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Total current liabilities	\$ 2,925	\$ 3,202
Deferred revenue	1,032	1,393
Credit facility with corporate partner	1,758	1,450
Capitalized lease	290	256
	-----	
Total liabilities	6,005	6,301
	-----	
Stockholders' equity	31,703	14,761
	-----	
Total liabilities and stockholders' equity	\$37,708	\$21,062
	=====	