

UNITED STATES
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

Date of Report (Date of earliest event reported) **February 20, 2003**



DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

000-26422

94-3171943

(State or other jurisdiction
of incorporation)

(Commission File
Number)

(IRS Employer
Identification No.)

350 Main Street, Suite 307, Doylestown, PA

18901

(Address of principal executive offices)

(Zip Code)

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

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

Item 5. Other Events and Regulation FD Disclosure

On February 20, 2003, Discovery Laboratories, Inc. (the "Registrant"), issued a news release updating the progress of its ongoing pivotal, landmark multinational Phase 3 clinical trial for Surfaxin[®] for Respiratory Distress Syndrome (RDS) in premature infants and reporting that the trial's completion was anticipated in October 2003 (the "RDS Progress Update News Release").

This Current Report on Form 8-K, including the exhibits, includes forward-looking statements within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934. Such forward-looking statements are based on current expectations and are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. For more information regarding potential risks, see the risk factors section of the Registrant's most recent reports on Form 10-K, Form 10-QSB and Form 10-Q on file with the Securities and Exchange Commission (the "Commission"). The Registrant undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date hereof.

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

(c) Exhibits

[99.1 The RDS Progress Update News Release.](#)

[99.2 The 2002 Year End Financial Results News Release](#) (as defined in item 9 below).

Item 9. Regulation FD Disclosure

On February 20, 2003, the Registrant issued a news release announcing financial results for the fourth quarter and year ended December 31, 2002, and providing selected updates on the Registrant's progress since the end of the third quarter 2002 (the "2002 Year End Financial Results News Release"). The information contained in this Item 9 and Exhibit 99.2 has not been audited by the Registrant's outside auditors.

The information contained in Item 9 of this Current Report on Form 8-K, including Exhibit 99.2, shall not be deemed to be incorporated by reference into the Registrant's filings with the Commission under the Securities Act of 1933.

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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: February 24, 2003

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Discovery Laboratories Updates Progress of Pivotal, Landmark Phase 3
Clinical Trial for Respiratory Distress Syndrome in Premature Infants

Doylestown, PA – February 20, 2003 - Discovery Laboratories, Inc. (Nasdaq: DSCO), a late-stage specialty pharmaceutical company leveraging its technology in humanized lung surfactants to develop novel respiratory therapies, announced today that it anticipates completing and announcing the results from its pivotal, landmark multinational Phase 3 clinical trial for Surfaxin[®] for Respiratory Distress Syndrome (RDS) in premature infants in October 2003, approximately four months later than originally communicated, with the New Drug Application to be filed with the FDA shortly thereafter.

The Company currently has 50 sites enrolling patients worldwide that comply with the Company's rigorous clinical site qualification processes and criteria necessary to participate in this pivotal, landmark clinical trial. Several additional sites were due to be added to the Company's existing qualified clinical trial site base by March 2003. Activating these additional sites was expected to position the Company to complete the landmark trial in May 2003. However, the Company's management decided not to include these substandard sites into its existing base of qualified clinical sites. This decision was reached after a thorough evaluation, and is consistent with the Company's stringent clinical site quality processes and criteria designed to provide the highest probability of success in this pivotal clinical trial to allow the introduction of the first humanized lung surfactant to market.

Based on a reevaluation and allowing for the Company's quality assurance and quality control activities, the Company's existing base of 50 qualified clinical sites should enroll and treat patients at a rate to announce results in October 2003. This landmark clinical trial is currently being conducted in Poland, Hungary, Mexico, Chile, Russia and Brazil, with Uruguay and Panama upcoming.

This pivotal, landmark clinical trial is to be conducted on approximately 1,500 patients and was designed as an event-driven, prophylaxis, superiority trial comparing the Company's lead product, Surfaxin, to an already approved surfactant, Exosurf[®]. Surfaxin is an engineered version of natural human lung surfactant and contains a humanized peptide, sinapultide, that is designed to precisely mimic the essential human lung surfactant protein B (SP-B). Exosurf, although the first approved synthetic surfactant, lacks any surfactant proteins, most noticeably protein SP-B. As a result, it is perceived to be inferior to other commercially available surfactants and its use is largely limited to outside of the U.S. and Western Europe. Survanta[®], the leading animal-derived product in the U.S., will serve as a reference arm in the landmark clinical trial. Survanta is made as an organic extract of bovine lung and contains some surfactant protein; however, its concentration of the essential surfactant protein SP-B can be highly variable and inconsistent.

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Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery stated, "We are convinced of the inherent pharmacology of Surfaxin and its superior profile compared to Exosurf and that the key to success is high quality execution. This landmark, pivotal clinical trial is intended to introduce the first humanized surfactant for respiratory medicine and be the springboard for our surfactant technology to treat a broad range of respiratory diseases. The Company could have made the decision to complete the clinical trial in May 2003; however, to do so would require us to compromise our stringent standards. Accordingly, we choose a course emphasizing quality clinical standards rather than one that would optimize enrollment rates."

The Company's procedure for site selection and qualification is quite extensive and consists of a number of critical evaluative steps before a site is allowed to enroll patients in the clinical trial. First, a preliminary evaluation of important medical and clinical conditions is conducted. A candidate site will next undergo on-site training by the Company's personnel of protocol and corresponding medical practices. Only after satisfactorily completing training, will the candidate site be allowed to engage in controlled, protocol-mandated medical and ventilatory procedures. If the candidate site satisfactorily performs these procedures, the site will be allowed to enroll one to two patients, on a probationary basis, with further evaluation of medical and clinical practices. Only with satisfactory compliance with the foregoing steps, will sites be allowed to commence full patient enrollment activities. Throughout the clinical trial, every site remains under the close scrutiny and supervision of the Company's medical monitors to ensure compliance with the study's protocol.

Surfactants are protein/lipid compositions that are produced naturally in the lungs and are critical to the lungs' ability to absorb oxygen. A lack or deficiency of surfactant is associated with several severe respiratory diseases including respiratory distress syndrome in premature infants (RDS), acute lung injury, acute respiratory distress syndrome, severe asthma, chronic obstructive pulmonary disease, among others. Currently available animal-derived surfactants have been effective in treating premature infants that lack surfactant, but several drawbacks and limitations of these products make it difficult for them to treat broader populations of RDS patients or expand into the broad respiratory disease markets. Because of this, RDS is the only indication for which surfactant products are currently approved. Presently, Discovery is developing the only humanized, engineered version of natural human lung surfactant that can be produced economically in large quantities as a high quality pharmaceutical without the risk of potential transmission of animal-borne diseases or adverse immunological reactions.

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About Discovery Laboratories, Inc.

Discovery Laboratories, Inc. is a specialty pharmaceutical company leveraging its platform technology in humanized lung surfactants to develop a number of potential novel respiratory therapies. Surfactants are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen. Discovery's technology is being developed initially for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. Surfaxin, Discovery's lead product, is currently in Phase 3 clinical trials for Respiratory Distress Syndrome (RDS) in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome (MAS) in full-term infants, and a Phase 2 clinical trial for Acute Respiratory Distress Syndrome (ARDS) in adults. Aerosol formulations are being developed in an effort to treat other respiratory conditions such as asthma, chronic obstructive pulmonary disease, acute lung injury and upper airway diseases such as sinusitis. Discovery is developing a dedicated sales and marketing capability through a collaboration with Quintiles for the United States, and has a strategic alliance with Esteve for Europe and Latin America. Interested parties can receive corporate updates by sending their email addresses to dsco@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, 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-KSB, 8-K, 10-QSB and 10-Q, and amendments thereto.

Discovery Laboratories Reports 2002 Year End Financial Results

Manufacturing of Surfaxin® for ARDS Trial to Recommence in March 2003

Doylestown, PA — February 20, 2003 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a late-stage specialty pharmaceutical company leveraging its technology in humanized lung surfactants to develop novel respiratory therapies today announced financial results for the fourth quarter and year ended December 31, 2002.

For the quarter ended December 31, 2002, the Company reported a net loss of \$5.3 million, or \$0.17 per share, on approximately 30.7 million weighted average shares outstanding, compared to a net loss of \$4.2 million, or \$0.17 per share, on approximately 25.0 million weighted average shares outstanding for the same period in 2001. For the year ended December 31, 2002, the Company reported a net loss of \$17.4 million, or \$0.64 per share, on approximately 27.4 million weighted average shares outstanding, compared to a net loss of \$11.1 million, or \$0.51 per share, on approximately 22.0 million weighted average shares outstanding at year end 2001.

The increase in the net loss primarily reflects clinical trial costs incurred for the Company's lead product, Surfaxin (which is currently in three Phase 3 trials and one Phase 2 trial for critical care patients with life threatening respiratory disorders), as well as activities related to the development of aerosolized formulations of the Company's humanized lung surfactant to potentially treat a variety of respiratory conditions. The results also include charges of \$193,000 and \$1,450,000 (for the quarter ended and twelve months ended December 31, 2002, respectively) for pre-launch commercialization activities for Surfaxin conducted for which funding is provided by a secured, revolving credit facility pursuant to a collaboration arrangement with Quintiles Transnational Corp. ("Quintiles"). Included in the year ended December 31, 2002, is a non-cash compensation charge of \$402,000 primarily related to the grant of stock options to non-employee members of the Board of Directors under the Automatic Option Grant program of the Company's Stock Option Plan and modifications to certain options held by three departing directors in connection with a reconfiguration of the Board. Additionally, included in the fourth quarter and year ended December 31, 2002, are charges of approximately \$428,000 and \$1.3 million, respectively, for reductions in prepaid expense balances primarily associated with research and development activities.

As of December 31, 2002, the Company had cash and investments of approximately \$19.2 million. 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. As of December 31, 2002, \$5.7 million was available for borrowing and \$1.45 was outstanding under the credit facility. In December 2002, the Company entered into a 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 December 31, 2002, the Company has used approximately \$285,000 of this financing arrangement. Our currently available financial resources will be adequate to satisfy our capital needs into the second quarter of 2004.

The increase in the weighted average number of shares outstanding in 2002 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 December 31, 2002 and December 31, 2001, there were approximately 32,857,000 and 25,546,000 common shares issued and outstanding, respectively.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented "This upcoming year presents a number of critical milestones for Discovery. The past year has prepared us for these opportunities. First, we put in place a high quality development infrastructure executing our four ongoing late-stage clinical trials of Surfaxin, with Phase 3 results in Respiratory Distress Syndrome (RDS) in premature infants and Phase 2 results in acute respiratory disease syndrome (ARDS) expected during 2003. The Company now has in place the sales and marketing capability to bring Surfaxin to the critical care markets in the United States, Europe and Latin America through our strategic relationships with Quintiles and Esteve. We announced very encouraging results, albeit in a small patient population, from Part A of our Phase 2 clinical trial of Surfaxin for ARDS, a life-threatening disorder for which there are currently no approved therapies anywhere in the world. Based on ever-increasing scientific evidence supporting the potential pipeline of opportunities for surfactant therapy for respiratory diseases, we launched our aerosol operations in Redwood City, California to develop aerosol formulations of our humanized lung surfactant and have already entered into two promising collaborations. Lastly, we closed a successful private financing with a group of well-recognized and sophisticated life sciences investors."

Selected updates on the Company's progress since the end of the third quarter 2002:

- In December, we reported that our contract manufacturer, Akorn, Inc., was experiencing certain operating difficulties in a production room primarily used for the filling of sterile pharmaceutical products and that they anticipated recommencing manufacture in February 2003. On February 18, 2003, Akorn advised the Company that this sterile production room has returned to full operational status. Surfaxin manufacturing for ARDS is expected to recommence in March 2003. The trial is ongoing and is

expected to return to full operational status in April 2003. The Company now anticipates completing Part B of its Phase 2 ARDS trial in the third quarter of 2003.

- The results from our pivotal, landmark multinational Phase 3 trial for Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants are anticipated to be available in October 2003, approximately four months later than originally communicated, with the New Drug Application to be filed with the FDA shortly thereafter. Several additional sites were due to be added to our existing qualified clinical trial site base beginning in late-January through March 2003. Activating these additional sites would have positioned us to complete the landmark trial in May 2003. However, management has recently made the decision not to include these sites into its existing base of qualified clinical sites. This decision was reached after a thorough evaluation and is consistent with our stringent clinical site quality processes and criteria designed to provide the highest probability of success in this pivotal trial to allow the introduction of the first humanized lung surfactant to market.

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- In November, we completed the sale of securities in a private placement to selected institutional and accredited investors for gross proceeds of approximately \$12.8 million. Approximately 6.4 million newly issued shares of Common Stock were sold at a price of \$1.94 per share. For an additional \$0.125 per underlying common share, the investors also purchased warrants exercisable for approximately 2.9 million shares of common stock with an exercise price of \$2.425 per share. The financing was led by BioAsia Investments, and included Heartland Value Fund, Special Situations Funds, SDS Capital Partners, DMG LLC, State Street Research Health Science Fund, PharmaBio Development, Inc. (the investment subsidiary of Quintiles Transnational Corp.), Laboratorios del Dr. Esteve S.A., and an accredited life science investor.
- Our Redwood City, California operations, launched in February 2002, achieved very encouraging preclinical results in the development of its proprietary humanized lung surfactant for aerosol use including the means to deliver therapeutically relevant dosages for novel respiratory therapies.

About Discovery Laboratories

Discovery Laboratories, Inc. is a specialty pharmaceutical company leveraging the only platform technology in humanized lung surfactants to develop a number of potential novel respiratory therapies. Surfactants are produced naturally in the lungs and are critical to all air-breathing mammals. Discovery's technology is being developed initially for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. Surfaxin, Discovery's lead product, is currently in Phase 3 clinical trials for Respiratory Distress Syndrome (RDS) in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome (MAS) in full-term infants, and a Phase 2 clinical trial for Acute Respiratory Distress Syndrome (ARDS) in adults. Aerosol formulations are being developed in an effort to treat other respiratory conditions including asthma, chronic obstructive pulmonary disease, acute lung injury and upper airway diseases such as sinusitis. Discovery is developing a dedicated sales and marketing capability through a collaboration with Quintiles for the United States, and has a strategic alliance with Esteve for Europe and Latin America. Interested parties can receive corporate updates by sending their email addresses to dsco@focuspartners.com.

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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, 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-KSB, 8-K, 10-QSB and 10-Q, and amendments thereto.

[\(Tables to follow\)](#)

Contacts:

John Cooper
CFO/SVP
215-340-4699

FOCUS Partners LLC
Harvey Goralnick/David Zazoff
212-752-9445

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

	Three months ended		For the years ended	
	December 31,		December 31,	
	(unaudited)			
	2002	2001	2002	2001
Revenues from collaborative agreements	\$ 394	\$ 197	\$ 1,782	\$ 1,112
Operating expenses:				
Research and Development	4,546	2,275	14,347	8,007
General and Administrative	1,155	2,295	5,458	5,067
Total expenses	5,701	4,570	19,805	13,074
Operating loss:	(5,307)	(4,373)	(18,023)	(11,962)
Other income and expense	50	161	580	816
Net Loss	\$ (5,257)	\$ (4,212)	\$ (17,443)	\$ (11,146)
Net loss per common share	\$ (0.17)	\$ (0.17)	\$ (0.64)	\$ (0.51)
Weighted average number of common shares outstanding	30,717	25,017	27,351	22,038

Condensed Consolidated Balance Sheets
 (in thousands)

	December 31,	
	2002	2001
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 8,538	\$ 3,758
Available-for-sale marketable securities	10,652	12,938
Prepaid expenses and other current assets	327	1,582
Total current assets	19,517	18,278
Property and equipment, net of depreciation	1,231	822
Other Assets	314	965
Total assets	\$21,062	20,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
Total current liabilities	\$ 3,202	\$ 1,794
Deferred revenue	1,393	615
Credit facility with corporate partner	1,450	-
Capitalized lease	256	33
Total liabilities	\$ 6,301	\$ 2,442