

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

February 23, 2006

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 February 23, 2006, Discovery Laboratories, Inc. (the “Company”) issued a press release announcing financial results for the fourth quarter and year ended December 31, 2005, and providing selected updates on the Company’s progress since the end of the third fiscal quarter in 2005. The full text of the press release is set forth in Exhibit 99.1 hereto.

Item 8.01. Other Events.

The Company has received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (“CHMP”) in relation to the Company’s European Marketing Authorization Application for Surfaxin[®] for the prevention and rescue treatment of Respiratory Distress Syndrome in premature infants. The Company plans to submit a written response to all of the CHMP’s outstanding issues in early April 2006 with a possible Oral Explanation before the CHMP in late June 2006. According to standard CHMP procedures, the Committee is expected to make a recommendation on whether to grant a Marketing Authorization for Surfaxin and issue a formal Opinion in late July 2006.

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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press release dated February 23, 2006.

The information in Item 2.02 of this Current Report on 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: March 1, 2006



Discovery Labs Reports Fourth Quarter 2005 Financial Results and Business Progress

Warrington, PA — February 23, 2006 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced financial results for the fourth quarter and year ended December 31, 2005. The Company will host a conference call Friday, February 24th at 10:00 AM EST. **The call in number is 866-332-5218.**

For the quarter ended December 31, 2005, the Company reported a net loss of \$29.4 million, or \$0.51 per share, on 57.8 million weighted average common shares outstanding, compared to a net loss of \$20.1 million, or \$0.42 per share, on 47.2 million weighted average shares outstanding for the same period in 2004. For the twelve months ended December 31, 2005, the Company reported a net loss of \$58.9 million, or \$1.09 per share, on 54.1 million weighted average shares outstanding, compared to a net loss of \$46.2 million, or \$1.00 per share, on 46.2 million weighted average shares outstanding for the same period in 2004. As of December 31, 2005, the Company had 61.0 million shares outstanding.

In December 2005, the Company purchased the manufacturing operations of Laureate Pharma, Inc. (Laureate) in Totowa, NJ for \$16.0 million and incurred additional related expenses of \$0.8 million. Included in the fourth quarter 2005 net loss is a charge, classified as in-process research and development, of \$16.8 million or \$0.29 per share related to the manufacturing purchase. Included in the fourth quarter 2004 net loss is a charge, classified as corporate partnership restructuring, of \$8.1 million, or \$0.17 per share, associated with the restructuring of strategic collaborations with Quintiles Transnational Corp. (Quintiles) and Laboratorios del Dr. Esteve S.A. (Esteve).

Excluding these charges, the net loss for the fourth quarter 2005 was \$12.6 million, or \$0.22 per share, compared to a net loss of \$11.9 million, or \$0.25 per share for the same period in 2004 and, for the twelve months ended December 31, 2005, the net loss was \$42.1 million, or \$0.78 per share, compared to a net loss of \$38.1 million, or \$0.82 per share, for the same period in 2004.

As of December 31, 2005, the Company had cash and marketable securities of \$50.9 million, a net increase of \$0.6 million from the previous quarter. Aggregate cash outflows for the fourth quarter were \$28.6 million, which consisted of \$12.6 million used in operating and investing activities and \$16.0 million for the purchase of the manufacturing operations of Laureate. These cash outflows were offset by aggregate cash inflows of \$29.2 million, which consisted of (i) a registered direct public offering resulting in net proceeds of \$18.9 million; (ii) a registered direct public offering to Esteve, resulting in net proceeds of \$4.5 million; (iii) a financing pursuant to the Company's Committed Equity Financing Facility (CEFF) resulting in net proceeds of \$3.2 million; and (iv) \$2.6 million, of which \$2.4 million was associated with financing the manufacturing purchase, from the use of the capital lease financing arrangement with General Electric Capital Corporation (GECC).

As of December 31, 2005, the Company had \$47.6 million available under the CEFF, subject to certain conditions. Additionally, under the Company's \$9.0 million capital lease financing arrangement with GECC, \$4.9 million is outstanding (\$1.6 million classified as current liabilities and \$3.3 million as long-term liabilities) and \$2.6 million remains available for use. The Company's \$8.5 million credit facility with Quintiles is fully outstanding, due in December 2006 and now classified as a current liability.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, “This past quarter, we believe we have significantly strengthened our Company, both financially and operationally in preparation for the potential FDA approval in April 2006 and U.S. commercial launch in the second quarter of 2006 of our lead product, Surfaxin[®]. We have raised \$29.0 million in capital, secured our own manufacturing operation -- a key strategic asset for Surfaxin and our pipeline, and are now in the final stage of building our specialty neonatal U.S. commercial capability. Important to the development of our surfactant replacement therapy (SRT) pipeline, we established a strategic alliance with Chrysalis Technologies (a division of Philip Morris USA) where we acquired rights to a novel aerosol generating technology being developed to enable the delivery of SRT to the deep lung. The successful application of our SRT and Chrysalis’ aerosol technology holds the promise, for the first time, of producing surfactant-based therapies that may revolutionize the treatment of serious respiratory conditions such as neonatal respiratory failure, acute lung injury, chronic obstructive pulmonary disorder, asthma, cystic fibrosis and others.”

Review of Operating Results - Three and Twelve Months Ended December 31, 2005

The Company reported a net loss of \$29.4 million and \$58.9 million for the three and twelve months ended December 31, 2005, respectively. Excluding the \$16.8 million charge in the fourth quarter of 2005 for the purchase of the manufacturing operation and the \$8.1 million charge in the fourth quarter of 2004 for the restructuring of strategic collaborations, the net loss increased by \$0.7 million and \$4.0 million for the three and twelve months ended December 31, 2005, respectively, as compared to the same periods in 2004. The change in the net loss is primarily due to:

- (i) manufacturing activities (included in research and development expenses) to support the production of clinical and commercial drug supply for the Company’s SRT programs, including Surfaxin, in conformance with current Good Manufacturing Practices (cGMPs). For the three and twelve months ended December 31, 2005, costs associated with these manufacturing activities were \$4.4 million and \$11.4 million, respectively, an increase of \$2.0 million and \$4.4 million compared to the same periods in 2004. Expenditures in 2005 for manufacturing activities include, but are not limited to, the implementation of enhancements to quality controls, process assurances and documentation requirements that support the production process predominantly at Laureate’s Totowa, NJ operation (the Company’s contract manufacturer at that time) in response to the FDA 483 inspectional observations. Additionally, the increase in expenses in the fourth quarter of 2005 were due to enhancements to Laureate’s Totowa, NJ operations and facility for the production of Surfaxin, SRT formulations and aerosol development capabilities. In December 2005, the Company purchased the manufacturing operation of Laureate in Totowa, NJ;
 - (ii) research and development activities related to the advancement of the Company’s SRT pipeline. For the three and twelve months ended December 31, 2005, costs associated with these activities, excluding manufacturing activities, were \$3.1 million and \$12.7 million, respectively, a decrease of \$1.6 million and \$6.1 million compared to the same periods in 2004. The decrease is primarily due to costs in 2004 associated with clinical and regulatory activities for Surfaxin for RDS, principally the NDA filing, a related milestone payment for the license of Surfaxin, and follow-up clinical activity pertaining to the two Phase 3 clinical trials. For the three and twelve months ended December 31, 2005, research and development activities primarily reflect regulatory activities associated with Surfaxin for RDS (specifically the U.S. FDA Approvable Letter and the EMEA Marketing Authorization Application) and clinical activities related to the Phase 2 clinical trials for Acute Respiratory Distress Syndrome (ARDS) in adults, Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants, and Aerosurf[™] for Neonatal Respiratory Failure;
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- (iii) pre-launch commercialization activities (included in general and administrative expenses) related to the Company building its own specialty pulmonary United States commercial organization to focus initially on the commercial and medical promise of its SRT to address respiratory therapies for the Neonatal Intensive Care Unit (NICU). Expenditures are for sales, marketing and medical affairs activities in anticipation of the potential approval and launch of Surfaxin for Respiratory Distress Syndrome (RDS) in the second quarter of 2006. For the three and twelve months ended December 31, 2005, costs associated with pre-launch commercialization activities were \$2.9 million and \$10.1 million, respectively, an increase of \$0.3 million and \$4.2 million compared to the same prior year periods;
- (iv) general and administrative activities in preparation for managing a fully-integrated commercial biotechnology organization. For the three and twelve months ended December 31, 2005, costs associated with these activities, excluding pre-launch commercialization activities, were \$2.4 million and \$8.4 million respectively, with no change compared to the three months ended December 31, 2004 and an increase of \$1.0 million compared to the twelve months ended December 31, 2004. These expenditures include building management and systems for financial and information technology capabilities, business development activities related to potential strategic collaborations, legal activities related to the preparation and filing of patents in connection with the expansion of our SRT pipeline, facilities expansion activities to accommodate existing and future growth, and corporate governance initiatives to comply with the Sarbanes-Oxley Act; and
- (v) the restructuring, in December 2004, of our strategic alliance with Esteve to develop, market and sell Surfaxin in Southern Europe. Revenues from this alliance decreased by \$0.1 million and \$1.1 million for the three and twelve months ended December 31, 2005, respectively, compared to the same prior year periods.

Selective Updates on Discovery's Business in Q4 2005

- In October, the U.S. Food and Drug Administration (FDA) accepted the Company's response to the Approvable Letter for Surfaxin for the prevention of RDS in premature infants. The FDA has established April 2006 as its target to complete its review of the Surfaxin NDA.
 - In December, the Company entered into a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc., for the Company to develop and commercialize aerosolized surfactant replacement therapies (aSRT) to address a broad range of serious respiratory conditions. This alliance focuses on therapies for hospitalized patients, including those in the NICU, pediatric intensive care unit and the adult intensive care unit, and can be expanded into other hospital applications and ambulatory settings. The Company and Chrysalis will utilize their respective capabilities and resources to support and fund the design and development of integrated drug-device systems that can be uniquely customized to address specific respiratory diseases and patient populations. Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. The Company is responsible for aSRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products. The Company has exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Chrysalis receives from the Company a tiered royalty, the base royalty applies to aggregate net sales of less than \$500 million, increases on aggregate net sales in excess of \$500 million, and increases again on aggregate net sales of alliance products in excess of \$1 billion.
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- In December, the Company acquired the manufacturing operation of Laureate in Totowa, NJ for \$16.0 million. The acquisition is intended to provide the Company with operational control and improved economics for the potential commercial and clinical production of Surfaxin and its SRT products. The Company's manufacturing operation is located in approximately 21,000 square feet of leased pharmaceutical manufacturing and development space that is specifically designed for the production of sterile pharmaceuticals in compliance with cGMP requirements.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that through its technology, pulmonary surfactants have the potential, for the first time, to address respiratory diseases where there are few or no approved therapies available.

Discovery Labs' SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the prevention and treatment of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants. Discovery Labs is preparing to conduct multiple Phase 2 pilot studies with Aerosurf[™], aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory failure.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery Labs is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, and other respiratory conditions.

For more information, please visit our corporate website 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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, 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. Among the factors which could affect Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery's internal sales and marketing organization will not be able to attract or maintain qualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by Discovery, 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 Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers and development partners to provide Discovery with adequate supplies of drug substance, drug products and expertise for completion of any of Discovery's clinical studies, risks relating to drug manufacturing by Discovery, risks relating to the integration of manufacturing operations into Discovery's existing operations, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, risks relating to the ability of the Company and its collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements, 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 Discovery'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
215-488-9490

Lisa Caperelli, Manager, Investor Relations
215-488-9413

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

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	(unaudited)			
	2005	2004	2005	2004
Revenues from collaborative agreements	\$ 29	\$ 134	\$ 134	\$ 1,209
Operating expenses:				
Research and development	7,477	7,037	24,137	25,793
General and administrative	5,323	4,958	18,505	13,322
In-process research & development	16,787	-	16,787	-
Corporate partnership restructuring	-	8,126	-	8,126
Total expenses	29,587	20,121	59,429	47,241
Operating loss	(29,558)	(19,987)	(59,295)	(46,032)
Other income / (expense)	202	(65)	391	(171)
Net loss	\$ (29,356)	\$ (20,052)	\$ (58,904)	\$ (46,203)
Net loss per common share	\$ (0.51)	\$ (0.42)	\$ (1.09)	\$ (1.00)
Weighted average number of common shares outstanding	57,843	47,236	54,094	46,179

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2005	December 31, 2004
<u>ASSETS</u>		
Current Assets:		
Cash and marketable securities	\$ 50,908	\$ 32,654
Prepaid expenses and other current assets	560	688
Total Current Assets	51,468	33,342
Property and equipment, net	4,322	4,063
Other assets	218	232
Total Assets	\$ 56,008	\$ 37,637
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 7,540	\$ 7,969
Credit facility	8,500	-
Capitalized leases and other liabilities, current portion	1,568	854
Total Current Liabilities	17,608	8,823
Long-Term Liabilities:		
Credit facility	-	5,929
Capitalized leases and other liabilities, long-term portion	3,562	1,788
Total Liabilities	21,170	16,540
Stockholders' Equity	34,838	21,097
Total Liabilities and Stockholders' Equity	\$ 56,008	\$ 37,637

