

**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**

**November 2, 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)

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))

**Item 1.01. Entry into a Material Definitive Agreement.**

On November 3, 2004, Discovery Laboratories, Inc. (the “Company”), and Quintiles Transnational Corp. (“Quintiles”), mutually agreed to restructure their business arrangements and terminate their commercialization agreements for Surfaxin(R), the Company’s lead product, in the United States. Pursuant to such restructuring, the Company will now have full commercialization rights for Surfaxin in the United States and the Company’s obligation to pay to Quintiles a commission on net sales in the United States of Surfaxin for the treatment of respiratory distress syndrome (RDS) and meconium aspiration syndrome (MAS) for 10 years following launch is terminated.

In connection with the foregoing, on November 3, 2004, the Company and PharmaBio Development Inc., Quintiles’ strategic investment group (“PharmaBio”), amended and restated the Loan Agreement dated as of December 10, 2001, between the Company and PharmaBio. Pursuant to the Amended and Restated Loan Agreement, the existing secured revolving credit facility of \$8.5 million with PharmaBio will remain available to the Company and the original maturity date of December 10, 2004, is now extended until December 31, 2006. Amounts to be drawn down under the credit facility will remain available up to the date of the commercial launch of Surfaxin. In addition, the Company and PharmaBio amended and restated the Security Agreement dated as of December 10, 2001, between the Company and PharmaBio in connection with the Loan Agreement and the Company issued a Promissory Note to PharmaBio which replaces and supercedes the note dated as of December 10, 2001, between the Company and PharmaBio.

Lastly, on November 3, 2004, the Company, Quintiles and PharmaBio entered into an Agreement which provides for, among other things, a limited preferred-provider arrangement.

The Company’s press release announcing the restructured business arrangements and the termination of the commercialization agreements for Surfaxin is attached hereto as Exhibit 99.1.

**Item 1.02. Termination of a Material Definitive Agreement.**

On November 3, 2004, in connection with the restructuring of the business arrangements and termination of the commercialization agreements for Surfaxin described in Item 1.01, the Company and Quintiles agreed to terminate the Commercialization Agreement dated as of December 10, 2001, between the Company and Quintiles, and the Investment and Commission Agreement dated as of December 10, 2001, between the Company and Quintiles.

The Company’s press release announcing the restructured business arrangements and the termination of the commercialization agreements for Surfaxin is attached hereto as Exhibit 99.1.

**Item 2.02. Results of Operations and Financial Condition.**

On November 4, 2004, the Company issued a press release to announce its financial results for the third quarter of 2004. The full text of the press release announcing such results is attached hereto as Exhibit 99.2 hereto.

**Item 3.02. Unregistered Sales of Equity Securities.**

On November 3, 2004, in connection with the restructuring of the business arrangements and termination of the commercialization agreements for Surfaxin described in Item 1.01, the Company issued 850,000 warrants to QFinance, Inc., a subsidiary of Quintiles, for no additional consideration, to purchase shares of the Company's common stock, par value \$0.001 per share, at an exercise price equal to \$7.19 per share. The warrants have a 10-year term and shall be exercisable for cash only. Expected total cash proceeds to the Company if exercised equal approximately \$6 million. The warrants are exercisable upon the earlier to occur of the FDA Approval Date (as defined below) and May 2, 2005. For purposes of the warrants, the FDA Approval Date means (i) the first date on which the FDA approves an application to market Surfaxin for any and all formulations and delivery mechanisms for the indications of RDS or MAS, or (ii) the first date on which the Company receives an "approvable letter" from the FDA with respect to the foregoing. The Company expects to take a charge against earnings equal to approximately \$4 million for the fourth quarter of 2004 in connection with the issuance of such warrants. The warrants were issued to PharmaBio in a private transaction exempt from registration pursuant to Section 4(2) of the Securities Act of 1933.

**Item 8.01. Other Events.**

On November 2, 2004, the Company issued a press release to announce that available funds under its existing capital lease financing facility with GE Healthcare Financial Services ("GE") have been increased by up to \$6.5 million. Including the \$2.5 million currently employed under the existing arrangement, the Company's lease line is now approximately \$9 million. Under the terms of the expanded financing arrangement, \$5 million is immediately available to the Company while an additional \$1.5 million remains subject to FDA approval to market the Company's lead product Surfaxin<sup>®</sup>, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Subject to the terms of the lease facility, GE will make the finances available for certain capital equipment purchases including manufacturing, information technology systems, laboratory, office and other related capital assets. The funds may be drawn down through September 2005 and are payable over three or four years, depending on the equipment. The full text of the press release is set forth in Exhibit 99.3 hereto.

**Item 9.01. Financial Statements and Exhibits.**

(c) Exhibits:

- 99.1 Press Release dated November 4, 2004.
- 99.2 Press Release dated November 4, 2004.
- 99.3 Press Release dated November 2, 2004.

## **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: November 4, 2004

## **Discovery Makes Strategic Moves to Pioneer Medical and Commercial Opportunities of Surfactant Replacement Therapy for Neonatology**

*Building Specialty U.S. Sales and Marketing Organization – Quintiles collaboration is restructured -- commercialization agreements terminated*

*Initiating Two Phase 2 Clinical Trials -- Surfaxin<sup>®</sup> for Bronchopulmonary Dysplasia and Aerosolized Surfactant to Treat Neonatal Respiratory Failures*

**Doylestown, PA — November 4, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO)** has undertaken a strategic initiative to optimize the inherent medical benefits and commercial promise of its Surfactant Replacement Therapy (SRT) to address the unmet need for respiratory therapies for the Neonatal Intensive Care Unit (NICU). Discovery is today announcing the restructuring of its business arrangements with Quintiles Transnational Corp., including the mutual termination of the related commercialization arrangements. Discovery is building its own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU and, as products are developed, to expand to critical care and hospital settings. This strategic initiative, led by the anticipated launch of Surfaxin<sup>®</sup>, is intended to allow Discovery to fully control its own sales and marketing operation, establish a strong presence in the NICU, and optimize company economics.

To enhance the potential commercial and medical value of SRT by addressing the most prevalent respiratory disorders in the NICU, Discovery is adjusting and broadening its pipeline of NICU therapeutic programs. Discovery is initiating a Phase 2 clinical trial for Neonatal Respiratory Failures utilizing aerosolized SRT administered through nasal continuous positive airway pressure (nasal CPAP) to reduce the need for invasive and costly mechanical ventilation and a Phase 2 clinical trial using Surfaxin to prevent Bronchopulmonary Dysplasia (BPD), a form of chronic lung disease. These respiratory conditions are cited as some of the most significant unmet medical needs for the neonatal community. Additionally, Discovery is focusing its efforts on its prophylactic approach to address meconium aspiration syndrome (MAS) which is being evaluated in a Phase 2 clinical trial and is discontinuing its Phase 3 clinical trial for the treatment of severe MAS.

**The company will host a conference call today at 11:00 AM EST. The call in number is 800-665-0669.**

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, “Our proprietary surfactant technology represents a new paradigm that we believe will revolutionize the treatment of respiratory diseases. For the first time, medical practitioners in the NICU can envision surfactant products that are precisely engineered to address various life-threatening respiratory diseases -- and a company capable of fulfilling a commitment to this community.”

“We believe our NICU pipeline could serve an addressable market estimated to be in excess of \$500 million per year in potential revenue to the Company. Starting with potential financial resources of approximately \$120 million, we are prepared to undertake this commitment while also advancing our critical care and hospital programs, notably led by our ARDS and aerosol programs,” continued Dr. Capetola.

## **Discovery Building its Own Sales and Marketing Capability -- Business Arrangements with Quintiles are Restructured and Commercialization Agreements Terminated**

On November 3, 2004, Discovery and Quintiles mutually agreed to restructure their business arrangements and terminate the commercialization agreements for Surfaxin in the United States. The terms are as follows:

- Discovery will now have full commercialization rights for Surfaxin in the United States. Under the agreement signed in 2001, Quintiles would have provided commercialization services for seven years post-launch, with an obligation to fund such services up to \$10 million per year. Discovery's obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of respiratory distress syndrome (RDS) and MAS for 10 years following launch is terminated.
- In connection with obtaining full commercialization rights for Surfaxin, Discovery has issued 850,000 warrants to PharmaBio Development Inc., Quintiles' strategic investment group, to purchase shares of Discovery common stock at an exercise price equal to \$7.19 per share. The warrants have a 10-year term and shall be exercisable for cash only with expected total proceeds to Discovery if exercised equal to approximately \$6 million. Discovery expects to take a charge against earnings equal to approximately \$4 million for the fourth quarter of 2004 in connection with the issuance of such warrants.
- The existing secured revolving credit facility of \$8.5 million with PharmaBio, will remain available to Discovery and the original maturity date of December 10, 2004, is now extended until December 31, 2006. Amounts to be drawn down under the credit facility will remain available up to the date of the commercial launch of Surfaxin.
- Discovery and Quintiles have entered into a limited preferred-provider arrangement.

Mark G. Osterman, Senior Vice President of Sales and Marketing of Discovery, commented, "Discovery intends to create a premier pulmonary specialty sales and marketing organization capable of delivering on the promise of SRT and with a strong commitment to the neonatal medical community. We begin with Surfaxin, which if approved, represents the first precision engineered surfactant with the potential to become a new worldwide standard of care for the prevention and treatment of RDS. Data from our Phase 3 RDS clinical trials demonstrated a highly significant reduction in RDS related mortality and an improvement in survival of infants without BPD. We plan to follow with novel, potentially first-in-class, engineered Surfactant Replacement Therapies for areas of critical unmet need."

## **Discovery Adjusts and Broadens its Pipeline for the NICU**

Dr. Fernando Moya, Richard W. Mithoff Professor of Pediatrics, Division of Neonatal-Perinatal Medicine at The University of Texas Medical School at Houston, a leading authority in neonatal medicine, stated, "Above and beyond the treatment of RDS with animal-derived surfactants, the neonatal medical community has long been challenged with means to adequately treat an array of other respiratory problems that beset fragile premature infants. These include chronic lung disease - also known as Bronchopulmonary Dysplasia (BPD), bronchiolitis, transient tachypnea, pneumonia, and a range of other conditions that lead to respiratory failure."

“Surfaxin, a precisely engineered surfactant with the most essential attributes of natural human lung surfactant, has demonstrated clinical results that are extremely encouraging for the medical community. Not only does this peptide-based technology hold the promise of improving the standard of care for treating RDS around the world, the medical community is clamoring to apply this technology to help these very vulnerable babies,” continued Dr. Moya.

Jay Greenspan, M.D., Professor & Vice Chairman of Pediatrics, Thomas Jefferson University, commented, “BPD remains a significant medical problem and demonstration that a surfactant therapy provides meaningful benefit for this population would be an important medical advance. Additionally, an aerosolized surfactant based therapy could transform the way surfactant is currently used. No currently available surfactants address these unmet needs.”

Discovery is adjusting its NICU pipeline in an effort to develop therapies that address the most prevalent respiratory disorders in the NICU and enhance the potential commercial and medical value of SRT in the following ways:

- Conducting a Phase 2 clinical trial for Surfaxin for the prevention of Bronchopulmonary Dysplasia (BPD), a serious form of chronic lung disease for which there is presently no approved drugs. This trial is expected to be initiated in the first quarter of 2005. Surfaxin, in its pivotal, landmark, multinational Phase 3 RDS prevention clinical trial, was the first surfactant to show statistical benefit in the reduction of BPD compared with another approved surfactant.

BPD is a costly syndrome that is associated with the prolonged use of mechanical ventilation and oxygen supplementation. BPD babies suffer from abnormal lung development and typically have a need for respiratory assistance -- oftentimes, for many months, as well as comprehensive care spanning years. According to the 1998 Division of Lung Disease and Office of Prevention Education and Control, the overall cost of treating infants with BPD in the United States is approximately \$2.4 billion. There are estimated to be between 10,000 to 25,000 babies that suffer from BPD per year in the United States alone, with the treatment of each patient costing up to \$250,000.

- Initiating a Phase 2 clinical trial for Neonatal Respiratory Failures utilizing aerosolized SRT via nasal CPAP in late fourth quarter of 2004. 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.

For the range of respiratory disorders experienced in the NICU for which limited treatments exist, neonatologists make every effort to avoid mechanically ventilating these patients. There is growing recognition by the neonatal medical community for the potential utility of a non-invasive method of delivering SRT to treat premature infants suffering from respiratory disorders including BPD, bronchiolitis, acute hypoxia, pneumonia, and transient tachypnea.

- Continuing our on-going Phase 2 prophylactic trial of Surfaxin for the treatment of MAS in full-term infants and discontinuing our Phase 3 clinical trial for Surfaxin for the treatment of MAS.

We believe an effective and affordable surfactant prophylactic therapy could significantly lower the risk to meconium-stained infants of chronic respiratory conditions and reduce the need for costly and invasive mechanical ventilation.

### **About Discovery Laboratories**

Discovery Laboratories, Inc. is a biopharmaceutical 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's technology produces a precisely engineered surfactant that is designed to closely mimic the essential properties of natural 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 patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

Discovery has filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin, the Company's lead product, for the prevention and treatment of RDS in premature infants. Discovery is also conducting various clinical programs to address ARDS in adults, BPD, a form of chronic lung disease in infants, Neonatal Respiratory Failures in premature infants, severe asthma in adults, and MAS in full-term infants.

More information about Discovery is available on the Company's Web site at [www.DiscoveryLabs.com](http://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 that the Company will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that the Company's internal sales and marketing organization will not succeed in developing market awareness of the Company's products, risk that the Company'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 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 Reports Third Quarter 2004 Financial Results

**Doylestown, PA — November 4, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today announced financial results for the third quarter of 2004. The Company will host a conference call today at 11:00 AM EST. The call in number is 800-665-0669.

For the quarter ended September 30, 2004, the Company reported a net loss of \$8.4 million, or \$0.18 per share, on 47.1 million weighted average common shares outstanding, compared to a net loss of \$6.2 million, or \$0.15 per share, on 41.1 million weighted average common shares outstanding for the same period in 2003. For the nine months ended September 30, 2004, the Company reported a net loss of \$26.2 million, or \$0.57 per share, on 45.8 million weighted average common shares outstanding, compared to a net loss of \$15.6 million, or \$0.43 per share, on 35.8 million weighted average common shares outstanding for the same nine-month period in 2003.

As of September 30, 2004, the Company had cash and marketable securities of approximately \$33.5 million, a decrease of \$7.8 million from the previous quarter. The decrease is primarily due to the use of approximately \$9.0 million for operating and investing activities offset by \$1.2 million of net proceeds from the use of existing credit and capital lease facilities. Additionally, the Company has a Committed Equity Financing Facility Agreement (CEFF) with Kingsbridge Capital Limited in which Kingsbridge is committed, subject to certain terms and conditions, to finance up to \$75 million of capital to support the Company's future growth. As of September 30, 2004, the Company had not engaged in any financing using the CEFF. Regarding the Company's debt facilities, as of September 30, 2004, approximately \$1.9 million was outstanding under the Company's \$9.0 million capital lease financing arrangement with GE Healthcare Financial Services and approximately \$5.7 million was outstanding under the Company's secured revolving credit facility of \$8.5 million with PharmaBio Development Inc., a subsidiary of Quintiles Transnational Corp.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of the Company, commented, "Our mission is to advance to market a pipeline of Surfactant Replacement Therapies that we believe will revolutionize the treatment of respiratory diseases. Our financing strategy has provided potential financial resources of approximately \$120 million to support this mission. Initially, we will build a fully-integrated company and a broad therapeutic portfolio that can address the most prevalent respiratory disorders experienced in the NICU."

"The recent major steps to terminate our collaboration with Quintiles, build our own United States sales and marketing organization, and adjust our pipeline are intended to enhance the commercial and medical value of our Surfactant Replacement Therapies, beginning with the potential launch of Surfaxin which is currently under review by the FDA and the European Medicines Evaluation Agency. Our lead program for the critical care and hospital settings is our Phase 2 clinical program for 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," continued Dr. Capetola.

## Review of Operating Results

The net loss of \$8.4 million and \$26.2 million for the three and nine months ended September 30, 2004, represents an increase of \$2.2 million and \$10.6 million respectively, compared to the same periods last year. This increase in the net loss is primarily due to:

- (i) manufacturing activities (included in research and development) to support the production of clinical and commercial drug supply, including Surfaxin<sup>®</sup>, the Company's lead product, for the Company's Surfactant Replacement Therapies (SRT) programs in conformance with current Good Manufacturing Practices (cGMPs). For the three and nine months ended September 30, 2004, costs associated with these manufacturing activities were \$1.1 million and \$4.6 million, a decrease of \$0.2 million and an increase of \$2.8 million, respectively, compared to the same periods last year;
- (ii) research and development activities related to the advancement of the Company's SRT pipeline, including, without limitation, regulatory filings for the Company's lead product, Surfaxin, and clinical trial activities related to the Phase 2b clinical trial for Acute Respiratory Distress Syndrome (ARDS) in adults. For the three and nine months ended September 30, 2004 costs associated with these related activities increased \$0.8 million and \$3.0 million, respectively, compared to the same periods last year;
- (iii) pre-launch commercialization activities to support the potential approval and launch of Surfaxin for Respiratory Distress Syndrome (RDS) (included in general and administrative expenses). These activities include, without limitation, sales and marketing management and medical affairs (including medical science liaisons). For the three and nine months ended September 30, 2004, costs associated with pre-launch commercialization activities were \$1.3 million and \$3.3 million, an increase of \$1.0 million and \$2.7 million, respectively, compared to the same periods last year. The majority of such costs are financed through the Company's secured, revolving credit facility with PharmaBio; and
- (iv) general and administrative activities primarily related to financial and information technology capabilities in preparation for the potential approval and launch of Surfaxin for RDS, legal activities related to the preparation and filing of patents in connection with the expansion of our SRT pipeline, and corporate governance initiatives in compliance with the Sarbanes-Oxley Act. For the three and nine months ended September 30, 2004 costs associated with these related activities increased \$0.5 million and \$2.0 million, respectively, compared to the same periods last year.

## SELECTED COMPANY UPDATES

**GE Healthcare Financial Services** – The Company's available funds under its existing capital lease financing facility with GE Healthcare Financial Services have been increased in November by up to \$6.5 million. Including the \$2.5 million currently employed under the existing arrangement, Discovery's lease line is now approximately \$9 million. Subject to the terms of the lease facility, GE will make the finances available for certain capital equipment purchases including manufacturing, information technology systems, laboratory, office and other related capital assets. The funds may be drawn down through September 2005 and are payable over three or four years, depending on the equipment.

**Quintiles U.S. Commercialization Arrangements** - Effective November 3, 2004, the Company terminated its arrangement with Quintiles to commercialize Surfaxin in the United States. In addition, Discovery is building its own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the Neonatal Intensive Care Unit (NICU) and, as products are developed, to expand to critical care and hospital settings.

- Discovery will now have full commercialization rights for Surfaxin in the United States. Under the agreement signed in 2001, Quintiles would have provided commercialization services for seven years post-launch, with an obligation to fund such services up to \$10 million per year. Discovery's obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of RDS and MAS for 10 years following launch is terminated.
- In connection with obtaining full commercialization rights for Surfaxin, Discovery has issued 850,000 warrants to PharmaBio to purchase shares of Discovery common stock at an exercise price equal to \$7.19 per share. The warrants have a 10-year term and shall be exercisable for cash only with expected total proceeds to Discovery if exercised equal to approximately \$6 million. Discovery expects to take a charge against earnings equal to approximately \$4 million in the fourth quarter of 2004 in connection with the issuance of such warrants.
- The existing secured revolving credit facility of \$8.5 million with PharmaBio, will remain available to Discovery and the original maturity date of December 10, 2004, is now extended until December 31, 2006. Amounts to be drawn down under the credit facility will remain available up to the date of the commercial launch of Surfaxin.

### **About Discovery Laboratories**

Discovery Laboratories, Inc. is a biopharmaceutical 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's technology produces a precisely engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of human 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 patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

Discovery has filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin, the Company's lead product, for the prevention and treatment of Respiratory Distress Syndrome in premature infants. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome in adults, Bronchopulmonary Dysplasia (BPD) in infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome in full-term infants.

More information about Discovery is available on the Company's Web site at [www.DiscoveryLabs.com](http://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 that the Company will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that the Company's internal sales and marketing organization will not succeed in developing market awareness of the Company's products, risk that the Company'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 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 September 30, 2004		Nine Months Ended September 30, 2004	
	2004	2003	2004	2003
Revenues from collaborative agreements	\$ 236	\$ 198	\$ 1,075	\$ 855
Operating expenses:				
Research and Development	5,673	5,096	18,757	12,950
General and Administrative	2,908	1,375	8,363	3,679
Total expenses	8,581	6,471	27,120	16,629
Operating loss	(8,345)	(6,273)	(26,045)	(15,774)
Other income (expense)	(37)	54	(106)	201
Net loss	\$ (8,382)	\$ (6,219)	\$ (26,151)	\$ (15,573)
Net loss per common share	\$ (0.18)	\$ (0.15)	\$ (0.57)	\$ (0.43)
Weighted average number of common shares outstanding	47,133	41,084	45,778	35,809

### Condensed Consolidated Balance Sheets

(in thousands)

	September 30, 2004	December 31, 2003
<b>ASSETS</b>		
Current assets:		
Cash, cash equivalents, and marketable securities	\$ 33,483	\$ 29,422
Prepaid expenses and other current assets	1,385	668
Total current assets	34,868	30,090
Property and equipment, net of depreciation	2,916	2,414
Other assets	1,807	211
Total Assets	\$ 39,591	\$ 32,715
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Credit facility with corporate partner	\$ 5,683	\$ 2,436
Other current liabilities	4,861	4,593
Total current liabilities	10,544	7,029
Deferred revenue	269	672
Capitalized lease	1,334	711
Total liabilities	12,147	8,412
Stockholders' equity	27,444	24,303
Total Liabilities and Stockholders' Equity	\$ 39,591	\$ 32,715

## **Discovery Laboratories Expands its Capital Lease Financing Facility with GE Healthcare Financial Services to approximately \$9 million**

**Doylestown, PA —November 2, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO)** today announced that available funds under its existing capital lease financing facility with GE Healthcare Financial Services have been increased by up to \$6.5 million. Including the \$2.5 million currently employed under the existing arrangement, Discovery's lease line is now approximately \$9 million.

Under the terms of the expanded financing arrangement, \$5 million is immediately available to Discovery while an additional \$1.5 million remains subject to FDA approval to market the company's lead product Surfaxin<sup>®</sup>, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Subject to the terms of the lease facility, GE will make the finances available for certain capital equipment purchases including manufacturing, information technology systems, laboratory, office and other related capital assets. The funds may be drawn down through September 2005 and are payable over three or four years, depending on the equipment.

John G. Cooper, Executive Vice President and Chief Financial Officer of Discovery commented, "The continued support from GE Healthcare Financial Services secures an important component of our financing strategy. Our business plan for 2005 includes the potential commercial launch of our lead product, Surfaxin for Respiratory Distress Syndrome in premature infants, and advancing the clinical development of our Acute Respiratory Distress Syndrome and key aerosol Surfactant Replacement Therapy programs. This capital lease financing facility will be used to invest in additional information technology systems such as sales, materials requirements planning and medical safety monitoring to support potential commercialization, and manufacturing capabilities for planned commercial and clinical requirements."

### **About Discovery Laboratories**

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) 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 patients where there are few or no approved therapies available. Discovery has filed a New Drug Application with the FDA and a Marketing Authorization Application with the EMEA for clearance to market Surfaxin, the Company's lead product, for the prevention and treatment of Respiratory Distress Syndrome in premature infants.

More information about Discovery is available on the Company's Web site at [www.DiscoveryLabs.com](http://www.DiscoveryLabs.com).

### **About GE Healthcare Financial Services, Life Science Finance**

GE Healthcare Financial Services, a unit of GE Commercial Finance, is the premier provider of capital, financial solutions and related services for the global healthcare market. With \$13 billion in assets, GE Healthcare Financial Services offers a full range of financing capabilities from equipment leasing and real estate financing to working capital lending, vendor programs and acquisition financing. The Life Science Finance group delivers innovative and flexible financing solutions to help customers preserve their cash and liquidity. For over a decade, GE Healthcare Financial Services has assisted life science companies large and small, from the first venture round to post-IPO. With a portfolio exceeding \$400 million, GE has

partnered with over 300 companies throughout the United States, Canada and Europe. For more information, visit [www.GEHealthcareFinance.com](http://www.GEHealthcareFinance.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.*

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