



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[®], 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.

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
ASSETS		
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
LIABILITIES AND STOCKHOLDERS' EQUITY		
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