



DISCOVERY LABORATORIES, INC.

Discovery Laboratories Reports Third Quarter Financial Results

- Top-line results for Surfaxin[®] RDS Pivotal Phase 3 trial expected this month -

Doylestown, PA — November 13, 2003 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases, reports financial results for the third quarter ended September 30, 2003 and selected updates.

For the quarter ended September 30, 2003, the Company reported a net loss of \$6.2 million, or \$0.15 per share, on approximately 41.1 million weighted average common shares outstanding, compared to a net loss of \$4.5 million, or \$0.17 per share, on approximately 26.4 million weighted average common shares outstanding for the same period in 2002. For the nine months ended September 30, 2003, the Company reported a net loss of \$15.6 million, or \$0.43 per share, on approximately 35.8 million weighted average common shares outstanding, compared to a net loss of \$12.2 million, or \$0.46 per share, on approximately 26.2 million weighted average common shares outstanding for the same period in 2002. The change in the net loss primarily reflects increased expenses for regulatory and clinical trial costs for the Company's lead product, Surfaxin[®], currently in Phase 3 and Phase 2 clinical trials, the transfer of Surfaxin manufacturing capabilities to a new contract manufacturing facility in connection with implementing the initial phase of a long-term manufacturing strategy, and development activities related to the Company's inhalable aerosol surfactant programs.

As of September 30, 2003, the Company had cash and investments of approximately \$35.9 million. The Company's cash position increased by \$0.4 million from the previous quarter due to \$6.2 million in proceeds received primarily from the redemption of certain warrants offset by \$5.8 million in net cash used for operations. During June and July of 2003, the Company's Common Stock attained certain exchange-related price performance thresholds permitting the Company to redeem (and thereby effectively compel the exercise of) three of its then outstanding classes of warrants (Class I, F and C) to purchase Common Stock. All of these warrants have been exercised, in accordance with their terms, either cashlessly or for cash, resulting in approximately 3.3 million shares of Common Stock issued and aggregate cash proceeds of \$6.1 million received by the Company.

Robert J. Capetola, Ph.D., President and CEO of the Company, stated, "This is a very exciting time for Discovery Labs. Our lead program and number one priority is the success of our landmark, pivotal Phase 3 superiority trial for Surfaxin for Respiratory Distress Syndrome in premature infants. We expect to announce top line results this month. We also have made significant progress in improving manufacturing capabilities to support commercialization requirements for RDS and late-stage clinical trials for our Acute Respiratory Distress Syndrome program. We anticipate initiating clinical trials of our aerosolized humanized surfactant

treatment for asthma in the near future. For the first time, through the application of our proprietary humanized surfactant technology, a pipeline of surfactant replacement therapies are being developed that have the potential to significantly improve the treatment of patients suffering from life-threatening respiratory disorders.”

Selected updates on the Company’s programs and progress:

- **Phase 3 Clinical Trials for Respiratory Distress Syndrome (RDS) in Premature Infants**
The Company expects to announce top-line trial results in November 2003 for its pivotal, multinational landmark Phase 3 clinical trial for Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants. This trial is designed to demonstrate the superiority of Surfaxin over the only commercially available synthetic surfactant and has a reference arm with an approved bovine (cow) derived surfactant.

In September 2003, at the 44th annual meeting of the European Society for Paediatric Research (ESPR) in Bilboa, Spain, leading neonatologists were presented with an analysis of the data from the Company’s successful supportive, non-inferiority Phase 3 clinical trial of Surfaxin for RDS in premature infants. This trial favorably compared the Company’s Surfaxin to Curosurf[®], an approved pig-lung extract and the current market leader in Europe.

- **Surfaxin Manufacturing**
The Company and Laureate Pharma, L.P. entered into a Technology Transfer and Manufacturing Agreement which provides for the establishment of a Surfaxin manufacturing line together with the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices (cGMP). The installation of this manufacturing line has been completed and production of drug supply remains on schedule. In addition, the agreement contemplates the installation and validation of a new Surfaxin manufacturing and filling line to produce large-scale commercial and clinical supplies of Surfaxin.
- **Capital Lease and Line of Credit Financing Arrangements**
In September 2003, the Company’s capital lease financing arrangement with the Life Science and Technology Finance Division of General Electric Capital Corporation was increased by \$3 million to provide, subject to certain conditions, up to \$4 million in financing for capital purchases. The Company intends to use this financing arrangement primarily to support the expansion of its manufacturing capabilities. As of September 30, 2003, the Company has used approximately \$765,000 of this financing arrangement.

The Company also has a secured revolving credit facility of \$8.5 to \$10.0 million with PharmaBio Development Inc., a subsidiary of Quintiles Transnational Corp., that is available for use through December 10, 2004. The Company intends to use this credit facility primarily for pre-launch commercialization purposes. As of September 30, 2003, \$5.7 million was available for borrowing and \$2.1 million was outstanding under the credit facility.

- **United States Patent on Surfactant Peptides**

In October 2003, a composition of matter patent was added to the Company's patent portfolio with the issuance of U.S. Patent No. 6,613,734. This patent covers a wide variety of combinations of peptides, proteins and other molecules related to the Company's proprietary humanized pulmonary surfactant technology and also includes methods of making and using the molecules.

About Discovery Laboratories

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes in infants and adults, Acute Lung Injury, asthma, Chronic Obstructive Pulmonary Disease and upper airway disorders. Surfaxin, Discovery's lead product, is in Phase 3 and Phase 2 clinical trials for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. 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 precisely 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 critical care and other hospitalized patients.

More information about Discovery Laboratories 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), risks relating to the progress of the Company's research and development, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with sufficient amounts of drug products for completion of any of the Company's clinical studies, other risks relating to the lack of sufficient drug product for completion of any of the Company's clinical studies, and risks relating to the development of competing therapies and/or technologies by other companies. Those associated risks and others are further described in the company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-KSB, 8-K, 10-Q and 10-QSB, and amendments thereto.

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(tables to follow)

Discovery Laboratories, Inc.
Condensed Consolidated Statements of Operations

(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues from collaborative agreements	\$ 198	\$ 368	\$ 855	\$ 1,388
Operating expenses				
Research and Development	5,096	3,475	12,950	9,801
General and Administrative	1,375	1,633	3,679	4,303
Total expenses	6,471	5,108	16,629	14,104
Operating loss	(6,273)	(4,740)	(15,774)	(12,716)
Other income and expense	54	211	201	530
Net loss	\$ (6,219)	\$ (4,529)	\$ (15,573)	\$ (12,186)
Net loss per common share	\$ (0.15)	\$ (0.17)	\$ (0.43)	\$ (0.46)
Weighted average number of common shares outstanding	41,084	26,441	35,809	26,223

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, <u>2003</u>	December 31, <u>2002</u>
ASSETS		
Current assets:		
Cash, cash equivalents and available-for-sale marketable securities	\$ 35,894	\$ 19,190
Prepaid expenses and other current assets	907	327
Total current assets	36,801	19,517
Property and equipment, net of depreciation	1,905	1,231
Other assets	275	314
Total assets	\$ 38,981	\$ 21,062
LIABILITIES AND STOCKHOLDERS' EQUITY		
Total current liabilities	\$ 3,950	\$ 3,202
Deferred revenue	852	1,393
Credit facility with corporate partner (long term portion)	2,065	1,450
Capitalized lease (long term portion)	485	256
Total liabilities	7,352	6,301
Stockholders' equity	31,629	14,761
Total liabilities and stockholders' equity	\$ 38,981	\$ 21,062