



DISCOVERY LABORATORIES, INC.

Discovery Laboratories Reports Fourth Quarter and Year End 2003 Financial Results

Surfaxin[®] Manufacturing for ARDS Trial Recommences

Doylestown, PA — March 16, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a biopharmaceutical company developing its proprietary humanized surfactant technology as Surfactant Replacement Therapies for respiratory diseases, today announced financial results for the fourth quarter and year ended December 31, 2003.

For the quarter ended December 31, 2003, the Company reported a net loss of \$8.7 million, or \$0.21 per share, on approximately 42.4 million weighted average shares outstanding, compared to a net loss of \$5.3 million, or \$0.17 per share, on approximately 30.7 million weighted average shares outstanding for the same period in 2002. For the year ended December 31, 2003, the Company reported a net loss of \$24.3 million, or \$0.65 per share, on approximately 37.4 million weighted average shares outstanding, compared to a net loss of \$17.4 million, or \$0.64 per share, on approximately 27.4 million weighted average shares outstanding at year end 2002. As of December 31, 2003 and December 31, 2002, there were approximately 42,491,000 and 32,818,000 common shares issued and outstanding, respectively.

As of December 31, 2003, the Company had cash of approximately \$29.4 million, a decrease of \$6.5 million from the previous quarter. In the quarter ended December 31, 2003, proceeds of \$1.2 million were received from the exercise of certain options and warrants, and approximately \$752,000 from existing credit lines were used by the Company for its commercial and manufacturing programs. The Company's cash position increased in 2003 by approximately \$10.3 million from the previous year. The increase in 2003 is primarily due to net proceeds of \$34.7 million received from the sale of securities and the exercise of certain options and warrants, offset by approximately \$23.5 million used for operating activities. As of December 31, 2003, \$5.7 million was available for borrowing under the Company's secured revolving credit facility of \$8.5 to \$10.0 million with PharmaBio Development Inc. of which \$2.4 million was outstanding. As of December 31, 2003, \$962,000 was outstanding under the Company's \$4 million capital lease financing arrangement with General Electric Capital Corporation.

The change in the net loss primarily reflects increased research and development expenses required to complete two Phase 3 clinical trials for the Company's lead product, Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, and for the Company's inhalable aerosol surfactant programs, including DSC-104 to treat patients with severe asthma. Additionally, the net loss reflects expenses of \$1.6 million and \$2.5 million (for the quarter ended and twelve months ended December 31, 2003, respectively) for the installation and validation of the Company's Surfaxin manufacturing and filling line at its new contract manufacturing facility for the production of clinical and commercial drug supply in conformance with current Good Manufacturing Practices. The net loss also includes charges of \$371,000 and \$986,000 (included in general and administrative expenses for

the quarter and twelve months ended December 31, 2003, respectively) for Surfaxin pre-launch commercialization activities for which funding is provided by a secured, revolving credit facility pursuant to the Company's collaboration arrangement with PharmaBio Development, Inc.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "This is a very exciting time for Discovery Labs. We are preparing the filing of our NDA for our lead product, Surfaxin for the treatment of Respiratory Distress Syndrome. We continue to optimize our manufacturing capabilities in order to support the potential commercialization of Surfaxin for RDS and clinical demand for our ongoing ARDS Phase 2 and potential Phase 3 programs. Our pipeline continues to expand as aerosolized formulations of our Surfactant Replacement Therapy (SRT) have entered the clinic. In the second half of 2004 we expect to initiate a Phase 2 clinical trial for DSC-104 for the treatment of severe asthma. Also serious respiratory problems, beyond RDS, are extremely prevalent in premature infants in Neonatal Intensive Care Units, and we are planning to initiate a Phase 2 clinical trial with our aerosol SRT to potentially treat premature infants suffering from respiratory dysfunctions."

Selected updates on the Company's programs and progress:

- **Manufacturing**

In the fourth quarter 2003, the Company and Laureate Pharma, L.P. entered into a Technology Transfer and Manufacturing Agreement for the establishment of a Surfaxin manufacturing and filling line at their facility for the production of clinical and commercial drug supply. All steps required for production of material in conformance with current Good Manufacturing Practices (cGMPs) have been completed. We are presently producing Surfaxin to support our Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults. Part B of this Phase 2 ARDS trial is ongoing and the Company expects to complete this program in the second half of 2004.

- **Phase 3 Clinical Trials for Respiratory Distress Syndrome (RDS) in Premature Infants**

During 2003, we completed and announced successful results from both a landmark, pivotal Phase 3 clinical trial and a supportive Phase 3 clinical trial of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants. We intend to use the results from these trials to form the basis for a new drug application (NDA) with the United States Food and Drug Administration as well as for regulatory applications for approval in the rest of the world. We expect to file the NDA in April 2004. The pivotal trial included 1,294 patients and was designed as a superiority trial to demonstrate the safety and efficacy of Surfaxin over Exosurf[®], an approved, non-protein containing synthetic surfactant. Survanta[®], a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the trial. The supportive, multinational Phase 3 clinical trial included 252 patients and was designed as a non-inferiority trial comparing Surfaxin to Curosurf[®], a pig-derived surfactant and the leading surfactant used in Europe.

- **DSC-104 for Asthma**

We recently completed a Phase 1b clinical trial to evaluate the safety, tolerability and deposition of our humanized lung surfactant, delivered as an inhaled aerosol (development name DSC-104) to treat individuals who suffer from asthma. This masked, placebo-controlled, randomized, Phase 1b study included six healthy subjects and eight mild-persistent asthmatic patients. Results

demonstrated that DSC-104 was safe and well tolerated, did not induce bronchospasm and was deposited to both the central and peripheral regions of the lungs in the mild-persistent asthmatic group and the healthy volunteers. We are preparing a Phase 2 dose escalation trial to be conducted at several leading asthma clinics in the US and anticipate initiating this trial in the second half of 2004.

▪ **Acute Respiratory Distress Syndrome (ARDS) in Adults**

In February 2004, the United States Food and Drug Administration (FDA) selected Surfaxin for the treatment of ARDS as the only applicant within the Division of Pulmonary and Allergy Drug Products to be included in its Continuous Marketing Application (CMA) Pilot 2 Program. Participation in this initiative is limited to one Fast Track product for each review division within the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research. This program was established to study and document the benefits of more frequent FDA feedback and interactions as a company moves through the various phases of development, with the goal that such interactions will expedite the development of Fast Track products.

About Discovery Laboratories

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies 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 critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery recently completed two Phase 3 clinical trials of Surfaxin, the Company's lead product, for the treatment of Respiratory Distress Syndrome in premature infants and is preparing to file new drug applications with the United States Food and Drug Administration and other regulatory authorities in the rest of the world. Our Surfactant Replacement Therapy is currently in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, as well as, a Phase 3 and Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants. Using aerosolized formulations of our Surfactant Replacement Therapy, we are preparing to initiate a Phase 2 trial for severe asthma (development name DSC-104) and a Phase 2 trial for Respiratory Dysfunction in premature 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 of delay in the Company's preparation and filing of applications for regulatory approval, 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. 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-KSB, 8-K, 10-Q and 10-QSB, and amendments thereto.

Company Contacts:

John G. Cooper, EVP, CFO

Kori Beer, IR & Communications

215-340-4699

Discovery Laboratories, Inc.

Condensed Consolidated Statement of Operations

(in thousands, except per share data)

	Three months ended		For the years ended	
	December 31, (unaudited)		December 31,	
	2003	2002	2003	2002
Revenues from collaborative agreements	\$ 183	\$ 394	\$ 1,037	\$ 1,782
Operating expenses:				
Research and Development	6,799	4,546	19,750	14,347
General and Administrative	2,043	1,155	5,722	5,458
Total expenses	<u>8,842</u>	<u>5,701</u>	<u>25,472</u>	<u>19,805</u>
Operating loss	(8,659)	(5,307)	(24,435)	(18,023)
Other income and expense	<u>(48)</u>	<u>50</u>	<u>155</u>	<u>580</u>
Net loss	<u>\$ (8,707)</u>	<u>\$ (5,257)</u>	<u>\$ (24,280)</u>	<u>\$ (17,443)</u>
Net loss per common share	\$ (0.21)	\$ (0.17)	\$ (0.65)	\$ (0.64)
Weighted average number of common shares outstanding	42,391	30,717	37,426	27,351

Condensed Consolidated Balance Sheets

(in thousands)

	December 31,	
	2003	2002
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 29,422	\$ 8,500
Available-for-sale marketable securities	-	10,652
Prepaid expenses and other current assets	<u>668</u>	<u>327</u>
Total current assets	30,090	19,479
Property and equipment, net of depreciation	2,414	1,231
Other assets	<u>211</u>	<u>352</u>
Total assets	<u>\$ 32,715</u>	<u>\$ 21,062</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Credit facility with corporate partner	\$ 2,436	\$ -
Other current liabilities	<u>4,593</u>	<u>3,202</u>
Total current liabilities	7,029	3,202
Deferred revenue	672	1,393
Credit facility with corporate partner	-	1,450
Capitalized lease	<u>711</u>	<u>256</u>
Total liabilities	<u>8,412</u>	<u>6,301</u>
Stockholders' equity	<u>24,303</u>	<u>14,761</u>
Total liabilities and Stockholders' Equity	<u>\$ 32,715</u>	<u>\$ 21,062</u>