



## Discovery Laboratories Reports First Quarter 2004 Financial Results

**Doylestown, PA — May 6, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO),** today announced financial results for the first quarter of 2004. The company will host a conference call today at 10:30 AM EDT. **The call in number is 800-665-0669.**

For the quarter ended March 31, 2004, the Company reported a net loss of \$8.9 million, or \$0.20 per share, on approximately 43.3 million weighted average shares outstanding, compared to a net loss of \$4.5 million, or \$0.14 per share, on approximately 32.9 million weighted average shares outstanding for the same period in 2003. As of March 31, 2004, the Company had cash of approximately \$23.6 million, a decrease of approximately \$5.9 million from the previous quarter. On April 2, 2004, the Company completed an underwritten public offering of 2.2 million shares of common stock resulting in net proceeds of approximately \$22.7 million.

The change in the net loss primarily reflects increased operating expenses for: (i) manufacturing activities, of which \$1.4 million is included in research and development, to support the production of clinical and commercial drug supply of the Company's Surfactant Replacement Therapies (including Surfaxin<sup>®</sup>) in conformance with current Good Manufacturing Practices (cGMPs); (ii) pre-launch commercialization activities for Surfaxin for the treatment of Respiratory Distress Syndrome (RDS) in premature infants, of which approximately \$936,000 and \$200,000 for the three months ended March 31, 2004 and 2003, respectively, are included in general and administrative costs; (iii) development and regulatory efforts for the Phase 3 clinical trials for Surfaxin for the treatment of RDS in premature infants for which a New Drug Application (NDA) was filed with the U.S. Food and Drug Administration (FDA) in April 2004; (iv) development activities for the Phase 2 clinical trial for Surfaxin for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults; and (v) research and development activities of aerosolized formulations of the Company's Surfactant Replacement Therapy (SRT) technology in preparation for the initiation of Phase 2 clinical trials (anticipated in the second half of 2004) for DSC-104 to potentially treat patients with severe, acute asthma and for aerosolized Surfaxin administered via nasal CPAP (continuous positive airway pressure) to potentially treat premature infants in the Neonatal Intensive Care Unit (NICU) suffering from Respiratory Dysfunction.

The decrease in cash of approximately \$5.9 million from the previous quarter is primarily due to approximately \$8.6 million of cash used for operating activities offset by (i) the use of approximately \$279,000 from an existing credit line with General Electric Capital Corporation to support manufacturing and other capital expenditures; (ii) the use of approximately \$829,000 from an existing credit line in connection with a collaboration agreement with PharmaBio Development Inc., a subsidiary of Quintiles Transnational Corp., to support pre-launch commercialization activities for Surfaxin for RDS; and (iii) approximately \$2.3 million received from the exercise of certain options and warrants. As of March 31, 2004, approximately \$1.4 million was outstanding under the Company's \$4 million capital lease financing arrangement with General Electric Capital Corporation. As of March 31, 2004, approximately \$3.3 million was outstanding under the Company's secured revolving credit facility of \$8.5 to \$10 million with PharmaBio Development Inc., and approximately \$5.7 million was available for borrowing.

As of March 31, 2004 and 2003, there were approximately 43,915,000 and 32,818,000 common shares issued and outstanding, respectively. After the public financing of April 2, 2004, there were approximately 46,115,000 common shares outstanding.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of the Company, commented, "Discovery's mission is to advance to market a pipeline of Surfactant Replacement Therapies which we believe will revolutionize the treatment of respiratory diseases. Our strategy is to build a therapeutic portfolio that addresses the range of respiratory disorders treated in the NICU, critical care and hospital settings. We significantly advanced our mission by the recent filing of an NDA for Surfaxin, our lead product, for the treatment of RDS and an opportunistic financing with three high quality life sciences institutional investors to improve our financial resources. This now positions us to address the commercial requirements for Surfaxin, if approved, and continue to optimize our manufacturing capabilities."

"We received a very enthusiastic response from leading neonatologists at the PAS Annual Meeting to our commitment to addressing respiratory diseases in the NICU, including Surfaxin and our planned Phase 2 program for aerosol SRT administered by nasal CPAP. Additionally, our SRT programs for use in hospital settings are progressing well. The ARDS program is now in full swing with the continued manufacture of clinical drug supply and expansion of our clinical infrastructure. For severe acute asthma, we expect to initiate a Phase 2 clinical trial for DSC-104 for the treatment of severe asthma. I believe, that with these programs, we have one of the broadest respiratory pipelines in the industry," continued Dr. Capetola.

Selected updates on the Company's programs and progress:

- **Surfaxin for RDS in premature infants**

On April 13, 2004, the Company submitted an NDA to the FDA for clearance to market Surfaxin for the prevention of RDS in premature infants. The NDA filing is supported, in large part, by data from the Company's two positive Phase 3 RDS clinical trials.

The Company is also preparing a Marketing Authorization Application (MAA) to be filed with the European Medicines Evaluation Agency (EMA) by the middle of 2004 for Surfaxin for the prevention and treatment of RDS. Recently, the Committee for Proprietary Medicinal Products (CPMP) determined that Surfaxin qualified for evaluation through the Centralized Procedure, a more streamlined European regulatory review process that allows for a single application, evaluation and authorization for the entire European Union.

On May 2, 2004, clinical trial results from the Company's two positive Phase 3 clinical trials of Surfaxin for the prevention of RDS were presented at the Pediatric Academic Societies' (PAS) Annual Meeting in San Francisco. The Pediatric Academic Societies consists of the American Pediatric Society, the Society for Pediatric Research and the Ambulatory Pediatric Association. The PAS Annual Meeting is recognized as the largest, most prestigious meeting dedicated to pediatric research and education in the world and brings together physicians with expertise in all areas of pediatrics. More than 5,000 pediatric healthcare providers, including approximately 1,100 neonatologists attended.

- **Underwritten Public Financing**

In April 2004, the Company completed an underwritten public offering of 2.2 million shares of common stock priced at \$11.00 per share resulting in gross and net proceeds to the Company of \$24.2 million and approximately \$22.7 million, respectively. Bear, Stearns and Co. Inc., acted as the lead manager of the offering. Three prominent healthcare/ biotechnology institutional investors participated in the offering.

- **Surfactant Replacement Therapy for Acute Respiratory Distress Syndrome (ARDS) in Adults**

In February 2004, the 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.

Part B of this Phase 2 ARDS trial is ongoing and the Company expects to complete this trial in the second half of 2004.

- **Manufacturing**

During the first quarter of 2004, the Company completed all steps required for the production of clinical and commercial drug supply of its Surfactant Replacement Therapies (including Surfaxin) in conformance with current Good Manufacturing Practices (cGMPs) at Laureate Pharma, L.P. The Company is presently producing Surfaxin to support its Phase 2 clinical trial for the treatment of ARDS in adults.

- **DSC-104 for Asthma**

The Company recently completed a Phase 1b clinical trial to evaluate the safety, tolerability and deposition of its 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. The Company is preparing a Phase 2 dose escalation trial to be conducted at several leading asthma clinics in the US and anticipates initiating this trial in the second half of 2004.

## **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 has filed a New Drug Application with the FDA for clearance to market Surfaxin, the Company's lead product, for the prevention of Respiratory Distress Syndrome in premature infants. Discovery is also conducting a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, Phase 3 and Phase 2 clinical trials for Meconium Aspiration Syndrome in full-term infants and (with aerosolized surfactant) is preparing to initiate a Phase 2 trial for 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](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 of delay in the Company's preparation and filing of applications for regulatory approval, risk of delay in the FDA's approval of any applications filed by the Company, risks of rejection of any applications filed by the Company, 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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## Discovery Laboratories, Inc.

### Condensed Consolidated Statement of Operations

(in thousands, except per share data)

	March 31, (unaudited)	
	2004	2003
Revenues from collaborative agreements	\$ 142	\$ 393
Operating expenses:		
Research and Development	6,710	3,844
General and Administrative	2,281	1,167
Total expenses	8,991	5,011
Operating loss	(8,849)	(4,618)
Other income and expense	(23)	113
Net loss	\$ (8,872)	\$ (4,505)
Net loss per common share	\$ (0.20)	\$ (0.14)
Weighted average number of common shares outstanding	43,320	32,857

### Condensed Consolidated Balance Sheets

(in thousands)

	March 31 2004	December 31 2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 23,564	\$ 29,422
Prepaid expenses and other current assets	560	668
Total current assets	24,124	30,090
Property and equipment, net of depreciation	2,878	2,414
Other assets	211	211
Total assets	\$ 27,213	\$ 32,715
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Credit facility with corporate partner	\$ 3,265	\$ 2,436
Other current liabilities	4,809	4,593
Total current liabilities	8,074	7,029
Deferred revenue	538	672
Capitalized lease	833	711
Total liabilities	9,445	8,412
Stockholders' equity	17,768	24,303
Total liabilities and stockholders' equity	\$ 27,213	\$ 32,715