



Discovery Labs Reports Fourth Quarter 2004 Financial Results and Business Progress

Warrington, PA — March 15, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced financial results for the fourth quarter and year ended December 31, 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 December 31, 2004, the Company reported a net loss of \$20.1 million, or \$0.42 per share, on 47.2 million weighted average common shares outstanding, compared to a net loss of \$8.7 million, or \$0.21 per share, on 42.4 million weighted average shares outstanding for the same period in 2003. Included in the fourth quarter 2004 results is a non-cash charge of \$8.1 million, or \$0.17 per share which is related to the restructuring of strategic partnerships with Quintiles Transnational Corp. (Quintiles) and Laboratorios del Dr. Esteve S.A. (Esteve). Net cash used for operating and investing activities in the fourth quarter of 2004 was \$8.6 million.

For the twelve months ended December 31, 2004, the Company reported a net loss of \$46.2 million, or \$1.00 per share, on 46.2 million weighted average shares outstanding, compared to a net loss of \$24.3 million, or \$0.65 per share, on 37.4 million weighted average shares outstanding for the same period in 2003.

As of December 31, 2004, the Company had cash and marketable securities of \$32.7 million, a net decrease of \$0.8 million from the previous quarter. Additionally, in February 2005, the Company completed a registered direct public offering resulting in net proceeds to the Company of \$27.5 million. The use of \$8.6 million for operating and investing activities in the fourth quarter of 2004 was offset by \$7.1 million of net proceeds from the use of the Company's Committed Equity Financing Facility (CEFF) and \$0.7 million from the use of existing credit and capital lease facilities. As of December 31, 2004, \$67.8 million was available, subject to certain conditions, under the CEFF.

As of December 31, 2004 approximately \$2.4 million was outstanding under the Company's \$9.0 million capital lease financing arrangement with General Electric Capital Corporation, and \$5.9 million was outstanding under the Company's secured credit facility of \$8.5 million with PharmaBio Development Inc., Quintiles strategic investment group. In association with the restructuring of the Company's business arrangements with Quintiles, the maturity date of this \$8.5 million credit facility was extended until December 31, 2006. Additionally, in February 2005, the Company accessed the remaining \$2.6 million available under the credit facility and currently the full \$8.5 million is outstanding.

Discovery Reacquires Key Marketing Rights in Fourth Quarter of 2004 ---- Building Specialty Commercial Organization for NICU Franchise

In November 2004, the Company reacquired its full United States commercialization rights for its lead product, Surfaxin[®] for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, by restructuring its business arrangements with Quintiles, including terminating the pre-existing commercialization agreements. The Company 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. This initiative is intended to allow the Company to fully control its own sales and marketing operation, establish a strong presence in the NICU, and optimize company economics. In connection with the restructuring, the Company issued to PharmaBio Development 850,000 warrants to purchase shares of Discovery common stock at an exercise price equal to \$7.19 per share. The Company incurred a \$4.0 million charge against earnings in connection with the restructured business arrangements.

In December 2004, the Company regained full commercialization rights in key European markets, Central America and South America for its Surfactant Replacement Therapy (SRT), including Surfaxin for RDS and Acute Respiratory Distress Syndrome (ARDS) in adults by restructuring its strategic alliance with Esteve. Under the revised collaboration, Esteve will focus on the key Southern European markets, and now has development and marketing rights to a broader portfolio of the Company's potential SRT products. The Company incurred a \$4.1 million charge against earnings, primarily in connection with the issuance of 500,000 shares of its common stock, at no cost to Esteve, in connection with regaining the commercial rights to these markets.

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. 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. The strategic initiatives we implemented in the fourth quarter are intended to allow Discovery to fully control our own sales and marketing operation in the United States, establish a strong presence and commitment to the NICU with the promise of multiple SRT products, and optimize company economics for our products worldwide.

"Surfaxin is the cornerstone of our Surfactant Replacement Therapy pipeline that is based upon our precision-engineered surfactant technology. Surfaxin has the potential to become the new standard of care for the treatment of RDS in premature infants. We have in hand an Approvable Letter for Surfaxin from the FDA. The organization is committed to resolving the issues at our drug product contract manufacturer and preparing for commercial launch in the first quarter of 2006. The recent financing strengthens our financial resources so that we can execute our business strategy for Surfaxin while advancing our NICU and hospital pipeline."

Selected Updates on Discovery's SRT Pipeline:

Neonatal Intensive Care Unit Indications:

- In February 2005, the Company received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. Importantly, the FDA is not requiring any additional preclinical or clinical trials for final approval. For approval, the Company must address primarily manufacturing issues raised by the FDA and finalize labeling details for the product. The Company anticipates resolving the manufacturing issues by July 2005, and launching Surfaxin in the first quarter of 2006. In October 2004, the Company submitted a Marketing Authorization Application (MAA) to the European Medicines Evaluation Agency (EMA) for Surfaxin for the treatment and prevention of RDS. The Company anticipates EMA approval in the first quarter of 2006.

- The Company broadened its SRT pipeline of therapeutic programs to address the most prevalent respiratory disorders with significant unmet medical needs for the neonatal community. In January 2005, a Phase 2 clinical trial was initiated to assess the safety and efficacy of delivering multiple doses of Surfaxin during the first two weeks of life for the prevention of Bronchopulmonary Dysplasia (BPD), a serious, chronic lung disease of newborn infants. Results from this trial are expected to be available in the first quarter of 2006. Also in January 2005, a Phase 2 pilot study was initiated to evaluate aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP) as a non-invasive means to potentially treat the broad range of neonatal respiratory failures that occur in the NICU. Results from this trial are expected to be available in the third quarter of 2005.

Critical Care / Hospital Indications

- In December 2004, the Company announced encouraging preliminary data from its Surfaxin Phase 2 clinical trial for the treatment of ARDS in adults. Based on this interim data and in consultation with leading clinical advisors, the ARDS Phase 2 protocol was modified to better establish the endpoint signal in key clinical outcomes so as to properly power and design a potential Phase 3 clinical trial. Results of the Phase 2 trial are expected to be available in the first quarter of 2006.

Review of Operating Results – Fourth Quarter and Year-End 2004

The Company reported a net loss of \$20.1 million and \$46.2 million for the three and twelve months ended December 31, 2004, respectively. This represents an increase of \$11.4 million and \$21.9 million, respectively, compared to the same prior year periods. Excluding the \$8.1 million charge in the fourth quarter of 2004 for the restructuring of strategic collaborations with Quintiles and Esteve, the net loss increased by \$3.3 million and \$13.8 million for the three and twelve months ended December 31, 2004, respectively, as compared to the same periods the prior year. This increase in the net loss is primarily due to:

- (i) pre-launch commercialization activities to support the potential approval and launch of Surfaxin for RDS (included in general and administrative expenses). These activities include, without limitation, sales and marketing management and medical affairs (including medical science liaisons). The Company is building its own specialty pulmonary United States sales and marketing organization to focus initially on the commercial and medical promise of its SRT to address respiratory therapies for the NICU. For the three and twelve months ended December 31, 2004, costs associated with pre-launch commercialization activities were \$2.6 million and \$5.9 million, an increase of \$2.2 million and \$4.9 million, respectively, compared to the same prior year periods;
- (ii) manufacturing activities (included in research and development) to support the production of clinical and commercial drug supply, including Surfaxin, for the Company's SRT programs in conformance with current Good Manufacturing Practices (cGMPs). For the three and twelve months ended December 31, 2004, costs associated with these manufacturing activities were \$2.4 million and \$7.0 million, an increase of \$0.4 million and \$2.7 million, respectively, compared to the same prior year periods;

- (iii) research and development activities related to the management and advancement of the Company's SRT pipeline, including, without limitation, clinical trial activities and regulatory filings for Surfaxin for RDS, clinical trial activities related to the Phase 2 clinical trial for ARDS in adults, and product development and clinical trial activities related to the Company's aerosol SRT programs. For the three and twelve months ended December 31, 2004, costs associated with research and development activities, excluding manufacturing activities, were \$4.6 million and \$18.8 million, a decrease of \$0.2 million and an increase of \$3.3 million, respectively, compared to the same prior year periods;
- (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, executive management and support infrastructure, legal activities related to the preparation and filing of patents in connection with the expansion of our SRT pipeline, facilities related costs to accommodate current and prepare for future growth, and corporate governance initiatives in compliance with the Sarbanes-Oxley Act. For the three and twelve months ended December 31, 2004, costs associated with these related activities were \$2.4 million and \$7.4 million, an increase of \$0.7 million and \$2.7 million, respectively, compared to the same prior year periods; and
- (v) non-cash charges incurred due to the modification of stock options held by a former executive officer of the Company and the vesting of certain stock options held by employees and consultants under the Company's Amended and Restated 1998 Stock Option Plan. For the three and twelve months ended December 31, 2004, these charges were \$0.8 million (of which \$0.6 million was included in research and development and \$0.2 million was included in general and administration) and \$1.3 million (of which \$0.8 million was included in research and development and \$0.5 million in general and administration), respectively.

About Discovery Labs

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 received an Approvable Letter from the FDA for Surfaxin, the Company's lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and has filed a Marketing Authorization Application with the EMEA for clearance to market Surfaxin in Europe. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome (ARDS) in adults, Bronchopulmonary Dysplasia (BPD) in premature infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome (MAS) 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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements 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 Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery 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 Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery'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 Discovery, 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 Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery'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 Discovery'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
215-488-9490

Lisa Caperelli, Investor Relations
215-488-9413

Consolidated Statement of Operations

(in thousands, except per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	(unaudited)			
	2004	2003	2004	2003
Revenues from collaborative agreements	\$ 134	\$ 183	\$ 1,209	\$ 1,037
Operating expenses:				
Research and development	7,037	6,799	25,793	19,750
General and administrative	4,958	2,043	13,322	5,722
Corporate partnership restructuring charges	8,126	-	8,126	-
Total expenses	20,121	8,842	47,241	25,472
Operating loss	(19,987)	(8,659)	(46,032)	(24,435)
Other income / (expense)	(65)	(48)	(171)	155
Net loss	\$ (20,052)	\$ (8,707)	\$ (46,203)	\$ (24,280)
Net loss per common share	\$ (0.42)	\$ (0.21)	\$ (1.00)	\$ (0.65)
Weighted average number of common shares outstanding	47,236	42,391	46,179	37,426

Consolidated Balance Sheets

(in thousands)

	December 31, 2004	December 31, 2003
ASSETS		
Current Assets:		
Cash, cash equivalents, and marketable securities	\$ 32,654	\$ 29,422
Prepaid expenses and other current assets	688	668
Total Current Assets	33,342	30,090
Property and equipment, net of depreciation	4,063	2,414
Other assets	232	211
Total Assets	\$ 37,637	\$ 32,715
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Credit facility, current portion	\$ -	\$ 2,436
Accounts payable and accrued expenses	8,823	4,593
Total Current Liabilities	8,823	7,029
Credit facility, non-current portion	5,929	-
Capitalized lease and deferred revenue	1,788	1,383
Total Liabilities	16,540	8,412
Shareholders' Equity	21,097	24,303
Total Liabilities and Shareholders' Equity	\$ 37,637	\$ 32,715