



Discovery Makes Strategic Moves to Pioneer Medical and Commercial Opportunities of Surfactant Replacement Therapy for Neonatology

Building Specialty U.S. Sales and Marketing Organization – Quintiles collaboration is restructured -- commercialization agreements terminated

Initiating Two Phase 2 Clinical Trials -- Surfaxin[®] for Bronchopulmonary Dysplasia and Aerosolized Surfactant to Treat Neonatal Respiratory Failures

Doylestown, PA — November 4, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO) has undertaken a strategic initiative to optimize the inherent medical benefits and commercial promise of its Surfactant Replacement Therapy (SRT) to address the unmet need for respiratory therapies for the Neonatal Intensive Care Unit (NICU). Discovery is today announcing the restructuring of its business arrangements with Quintiles Transnational Corp., including the mutual termination of the related commercialization arrangements. Discovery is building its own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the NICU and, as products are developed, to expand to critical care and hospital settings. This strategic initiative, led by the anticipated launch of Surfaxin[®], is intended to allow Discovery to fully control its own sales and marketing operation, establish a strong presence in the NICU, and optimize company economics.

To enhance the potential commercial and medical value of SRT by addressing the most prevalent respiratory disorders in the NICU, Discovery is adjusting and broadening its pipeline of NICU therapeutic programs. Discovery is initiating a Phase 2 clinical trial for Neonatal Respiratory Failures utilizing aerosolized SRT administered through nasal continuous positive airway pressure (nasal CPAP) to reduce the need for invasive and costly mechanical ventilation and a Phase 2 clinical trial using Surfaxin to prevent Bronchopulmonary Dysplasia (BPD), a form of chronic lung disease. These respiratory conditions are cited as some of the most significant unmet medical needs for the neonatal community. Additionally, Discovery is focusing its efforts on its prophylactic approach to address meconium aspiration syndrome (MAS) which is being evaluated in a Phase 2 clinical trial and is discontinuing its Phase 3 clinical trial for the treatment of severe MAS.

The company will host a conference call today at 11:00 AM EST. The call in number is 800-665-0669.

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. For the first time, medical practitioners in the NICU can envision surfactant products that are precisely

engineered to address various life-threatening respiratory diseases -- and a company capable of fulfilling a commitment to this community.”

“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. Starting with potential financial resources of approximately \$120 million, we are prepared to undertake this commitment while also advancing our critical care and hospital programs, notably led by our ARDS and aerosol programs,” continued Dr. Capetola.

Discovery Building its Own Sales and Marketing Capability -- Business Arrangements with Quintiles are Restructured and Commercialization Agreements Terminated

On November 3, 2004, Discovery and Quintiles mutually agreed to restructure their business arrangements and terminate the commercialization agreements for Surfaxin in the United States. The terms are as follows:

- 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 respiratory distress syndrome (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 Development Inc., Quintiles’ strategic investment group, 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 for 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.
- Discovery and Quintiles have entered into a limited preferred-provider arrangement.

Mark G. Osterman, Senior Vice President of Sales and Marketing of Discovery, commented, “Discovery intends to create a premier pulmonary specialty sales and marketing organization capable of delivering on the promise of SRT and with a strong commitment to the neonatal medical community. We begin with Surfaxin, which if approved, represents the first precision engineered surfactant with the potential to become a new worldwide standard of care for the prevention and treatment of RDS. Data from

our Phase 3 RDS clinical trials demonstrated a highly significant reduction in RDS related mortality and an improvement in survival of infants without BPD. We plan to follow with novel, potentially first-in-class, engineered Surfactant Replacement Therapies for areas of critical unmet need.”

Discovery Adjusts and Broadens its Pipeline for the NICU

Dr. Fernando Moya, Richard W. Mithoff Professor of Pediatrics, Division of Neonatal-Perinatal Medicine at The University of Texas Medical School at Houston, a leading authority in neonatal medicine, stated, “Above and beyond the treatment of RDS with animal-derived surfactants, the neonatal medical community has long been challenged with means to adequately treat an array of other respiratory problems that beset fragile premature infants. These include chronic lung disease - also known as Bronchopulmonary Dysplasia (BPD), bronchiolitis, transient tachypnea, pneumonia, and a range of other conditions that lead to respiratory failure.”

“Surfaxin, a precisely engineered surfactant with the most essential attributes of natural human lung surfactant, has demonstrated clinical results that are extremely encouraging for the medical community. Not only does this peptide-based technology hold the promise of improving the standard of care for treating RDS around the world, the medical community is clamoring to apply this technology to help these very vulnerable babies,” continued Dr. Moya.

Jay Greenspan, M.D., Professor & Vice Chairman of Pediatrics, Thomas Jefferson University, commented, “BPD remains a significant medical problem and demonstration that a surfactant therapy provides meaningful benefit for this population would be an important medical advance. Additionally, an aerosolized surfactant based therapy could transform the way surfactant is currently used. No currently available surfactants address these unmet needs.”

Discovery is adjusting its NICU pipeline in an effort to develop therapies that address the most prevalent respiratory disorders in the NICU and enhance the potential commercial and medical value of SRT in the following ways:

- Conducting a Phase 2 clinical trial for Surfaxin for the prevention of Bronchopulmonary Dysplasia (BPD), a serious form of chronic lung disease for which there is presently no approved drugs. This trial is expected to be initiated in the first quarter of 2005. Surfaxin, in its pivotal, landmark, multinational Phase 3 RDS prevention clinical trial, was the first surfactant to show statistical benefit in the reduction of BPD compared with another approved surfactant.

BPD is a costly syndrome that is associated with the prolonged use of mechanical ventilation and oxygen supplementation. BPD babies suffer from abnormal lung development and typically have a need for respiratory assistance -- oftentimes, for many months, as well as comprehensive care spanning years. According to the 1998 Division of Lung Disease and Office of Prevention Education and Control,

the overall cost of treating infants with BPD in the United States is approximately \$2.4 billion. There are estimated to be between 10,000 to 25,000 babies that suffer from BPD per year in the United States alone, with the treatment of each patient costing up to \$250,000.

- Initiating a Phase 2 clinical trial for Neonatal Respiratory Failures utilizing aerosolized SRT via nasal CPAP in late fourth quarter of 2004. We believe that this approach represents a non-invasive surfactant-based therapy for premature infants and has the potential to reduce the need for and complications from mechanical ventilation, including lowering the risk of infection.

For the range of respiratory disorders experienced in the NICU for which limited treatments exist, neonatologists make every effort to avoid mechanically ventilating these patients. There is growing recognition by the neonatal medical community for the potential utility of a non-invasive method of delivering SRT to treat premature infants suffering from respiratory disorders including BPD, bronchiolitis, acute hypoxia, pneumonia, and transient tachypnea.

- Continuing our on-going Phase 2 prophylactic trial of Surfaxin for the treatment of MAS in full-term infants and discontinuing our Phase 3 clinical trial for Surfaxin for the treatment of MAS.

We believe an effective and affordable surfactant prophylactic therapy could significantly lower the risk to meconium-stained infants of chronic respiratory conditions and reduce the need for costly and invasive mechanical ventilation.

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 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 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 RDS in premature infants. Discovery is also conducting various clinical programs to address ARDS in adults, BPD, a form of chronic lung disease in infants, Neonatal Respiratory Failures in premature infants, severe asthma in adults, and 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 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.

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