



## **Discovery Labs Forms a Strategic Alliance with Chrysalis Technologies to Develop Aerosolized Surfactant Replacement Therapies for Respiratory Diseases**

*Combination of precision-engineered lung surfactant and robust aerosolization technology holds promise to revolutionize respiratory medicine*

**Conference Call Monday, December 12 at 10:00 AM EST -- 866-332-5218**

**Warrington, PA, December 11, 2005** — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, entered into a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc., for Discovery Labs to develop and commercialize aerosolized surfactant replacement therapies (aSRT) to address a broad range of serious respiratory conditions. This alliance unites two highly complementary respiratory technologies -- Discovery Labs' precision-engineered surfactant technology that mimics the most important attributes of human lung surfactant, with Chrysalis' novel aerosolization device technology that is being developed to enable the delivery of therapeutics to the deep lung. The successful application of these two proprietary technologies holds the promise, for the first time, of producing surfactant-based therapies that may revolutionize the treatment of serious respiratory conditions such as acute lung injury, neonatal respiratory failure, chronic obstructive pulmonary disorder, asthma, cystic fibrosis and others.

The alliance focuses on therapies for hospitalized patients, including those in the neonatal intensive care unit (NICU), pediatric intensive care unit (PICU) and the adult intensive care unit (ICU), and can be expanded into other hospital applications and ambulatory settings. Discovery Labs and Chrysalis will utilize their respective capabilities and resources to support and fund the design and development of integrated drug-device systems that can be uniquely customized to address specific respiratory diseases and patient populations. Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. Discovery Labs is responsible for aSRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products. Discovery has exclusive rights to Chrysalis' aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Chrysalis receives from Discovery Labs a tiered royalty, the base royalty applies to aggregate net sales of less than \$500 million, increases on aggregate net sales in excess of \$500 million, and increases again on aggregate net sales of alliance products in excess of \$1 billion.

Surfactants are substances that are produced naturally in the lungs, are essential for proper breathing, and their dysfunction is associated with serious respiratory diseases. Up to now the medical community has been unable to utilize the full potential of surfactant replacement therapies. Currently available surfactants are animal-derived which limits their broad use including the lack of ability to produce therapeutically meaningful aSRT. Discovery's technology is a precision-engineered pulmonary surfactant capable of being formulated to produce aerosols that retain their essential therapeutic properties allowing for the development of a potentially broad portfolio of aSRT products. Chrysalis' technology is designed with the potential to enable or enhance the delivery of such compounds to the deep lung.

Steven M. Donn, M.D., Professor of Pediatrics, Director, Neonatal-Perinatal Medicine at the University of Michigan Health System commented, “An aerosolized surfactant based therapy could transform the way the neonatal medical community addresses the array of respiratory problems that beset fragile premature infants. Presently, neonatologists have limited pharmacologic options to treat neonatal respiratory failure with many infants suffering significant morbidity and requiring costly treatments and prolonged hospital stays. Aerosolized surfactant replacement therapy represents a novel therapeutic approach that the medical community eagerly anticipates applying to help these very vulnerable babies.”

Michael Matthay, M.D., Professor of Medicine and Anesthesia at the University of California, San Francisco and an internationally renowned expert in pulmonary critical care medicine, commented, “Increasingly, the medical community has focused on a comprehensive strategy to treat serious respiratory disease such as those treated by the National Heart Lung Blood Institute ARDS NETWORK, an association of clinicians and hospitals supported by the NIH to treat a life-threatening respiratory disease, acute respiratory distress syndrome (ARDS). As a component of implementing a Lung Protection Strategy, the possibility of having a novel precision-engineered surfactant delivered as an aerosol for patients early in the disease process is exciting. Additionally, this combined technology may serve as a system for pulmonary drug delivery.”

### **Chrysalis Technologies Aerosol Generation Technology**

Chrysalis Technologies has developed a proprietary aerosol generation technology that is being designed with the potential to enable targeted upper respiratory or deep lung delivery of therapies for local or systematic applications. The Chrysalis technology (covered by over 40 patents and patent applications) is designed to produce high-quality, low velocity aerosols for possible deep lung aerosol delivery. Aerosols are created by pumping the drug formulation through a small, heated capillary wherein the excipient system is substantially converted to the vapor state. Upon exiting the capillary, the vapor stream quickly cools and slows in velocity yielding a dense aerosol with a defined particle size. The defined particle size can be readily controlled and adjusted through device modifications and drug formulation changes.

### **Discovery Labs’ Surfactant Replacement Technology**

Surfactants are protein and lipid (fat) compositions that are produced naturally in the lungs and are critical to all air-breathing mammals. They cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways which lead to the air sacs. Discovery Labs’ surfactant product candidates contain a precision-engineered peptide that is designed to closely mimic the essential attributes of human surfactant protein B (SP-B), the protein that is most important for the proper functioning of the respiratory system. Discovery Labs’ SRT has the ability to be precisely formulated to address various medical indications.

Discovery Labs’ SRT technology was invented at The Scripps Research Institute, was further developed by Johnson & Johnson, and is exclusively licensed to Discovery Labs. The Company’s lead product, Surfaxin<sup>®</sup>, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Aerosurf<sup>™</sup>, the Company’s lead aerosol product, has recently completed a pilot Phase 2 clinical trial to address neonatal respiratory failure.

Robert J. Capetola, Ph.D., President and CEO of Discovery Labs, commented, “Aerosolized surfactant replacement therapy that can be reliably and consistently delivered deep into patients’ lungs has the

potential to transform respiratory medicine. Based on the successes we have realized to this point, we are confident about the potential of our surfactant technology -- we anticipate FDA approval of our lead product, Surfaxin for RDS in April 2006; our scientists have demonstrated that our SRT can be aerosolized at the proper particle size with the fluid dynamics capable of penetrating the deep lung; and we have successfully completed pilot Phase 2 clinical studies of our aerosolized SRT in neonates with RDS and in adults with mild to moderate asthma. To capitalize on this opportunity, it is necessary to combine our SRT technology with a robust aerosol generation technology into a comprehensive systems approach that can be engineered into products that provide optimal delivery to the lungs, functional patient interfaces and ease of use by medical practitioners.

During the past two years, our scientific team has assessed several aerosol generating technologies. This alliance is the culmination of a comprehensive feasibility evaluation, that took place over the last year, which successfully demonstrated the capabilities of Chrysalis' technology. Chrysalis' technology demonstrated an ability to consistently and reliably deliver, over extended periods of time, aerosolized surfactant at output rates that we believe are appropriate for therapeutic utility in neonates, children and adults. We now have access to a leading aerosolization technology with the product development and engineering expertise of Chrysalis -- thus strengthening our capabilities to achieve our vision. Beginning in 2006, we will further advance our pipeline of aerosolized surfactant replacement therapies, starting with our lead aerosol product, Aerosurf."

### **The Lead Program -- Aerosurf<sup>®</sup> for the NICU**

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in the NICU. There are approximately 1.5 million premature infants born annually worldwide at risk for respiratory problems associated with surfactant dysfunction. Neonatologists generally try to avoid mechanically ventilating these patients because doing so requires intubation (the invasive process of inserting a breathing tube down the trachea). Noted neonatologists have commented on the potential utility of a non-invasive method of delivering SRT to treat premature infants suffering from an array of respiratory disorders.

Aerosurf is Discovery Labs' precision-engineered aerosolized SRT administered via nasal continuous positive airway pressure (nCPAP) to treat premature infants at risk for respiratory failure. In September 2005, Discovery Labs completed and announced the results of a pilot Phase 2 clinical study of Aerosurf which was designed to evaluate its feasibility, safety and tolerability for the prevention of RDS in premature infants. The study demonstrated that it is feasible to deliver Aerosurf via nCPAP and the treatment was generally safe and well tolerated. The Phase 2 study of Aerosurf did not include the Chrysalis technology.

Discovery Labs and Chrysalis believe that the combination of their respective technologies and expertise can develop a systems approach to optimize the therapeutic application of Aerosurf for neonatologists to treat premature infants suffering from respiratory failure. Discovery Labs anticipates conducting multiple Phase 2 clinical studies of Aerosurf in 2006.

Aerosurf is an investigational drug that has not been approved by the U.S. FDA or any other world health regulatory authorities.

### **Conference Call Details**

Discovery Labs will hold a conference call Monday at 10:00 AM EST to further discuss in greater detail the foregoing. The call in number is 866-332-5218. The international call in number is 706-

679-3237. This audio webcast will be available to shareholders and interested parties through a live broadcast on the Internet at <http://audioevent.mshow.com/262604> and [www.discoverylabs.com](http://www.discoverylabs.com). It is recommended that participants log onto one of these sites at least 15 minutes prior to the call. The Internet broadcast will be available for up to 30 days after the call at both website addresses. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 2880078.

### **About Chrysalis Technologies**

In 2000, Chrysalis Technologies Inc. was established as a subsidiary of Altria Group, Inc. Since January of 2005, the former operations of Chrysalis have been a business division of Philip Morris USA (PM USA), a wholly owned subsidiary of Altria Group, Inc. Chrysalis has developed its aerosol generation platform for pulmonary drug delivery and is focused on the development and commercialization of this technology.

Altria Group, Inc. (NYSE: MO) owns approximately 86.5% of the outstanding common shares of Kraft Foods Inc. and 100% of the outstanding common shares of Philip Morris International Inc., Philip Morris USA Inc. and Philip Morris Capital Corporation. Altria Group, Inc. recorded 2004 net revenues of \$89.6 billion.

### **About Discovery Labs**

Discovery Laboratories, Inc. is a biotechnology 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 precision-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 address respiratory diseases where there are few or no approved therapies available.

Discovery's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin<sup>®</sup>, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the prevention and treatment of Chronic Lung Disease (CLD) in premature infants. Aerosurf<sup>™</sup>, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), is for the treatment of neonatal respiratory failure.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, and other respiratory conditions.

Under the terms of our arrangements with Chrysalis, Discovery will be responsible for manufacturing any of the potential combination drug-device products that we may pursue. To successfully do so, Discovery will need to develop and implement certain manufacturing and technical capabilities necessary to take advantage of the relevant Chrysalis aerosolization technology and know-how that is being licensed by Discovery.

For more information, please visit our corporate website 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 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 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 and development partners to provide Discovery with adequate supplies of drug substance, drug products and expertise 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, risks relating to the ability of the Company and its collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements, 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.*

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