



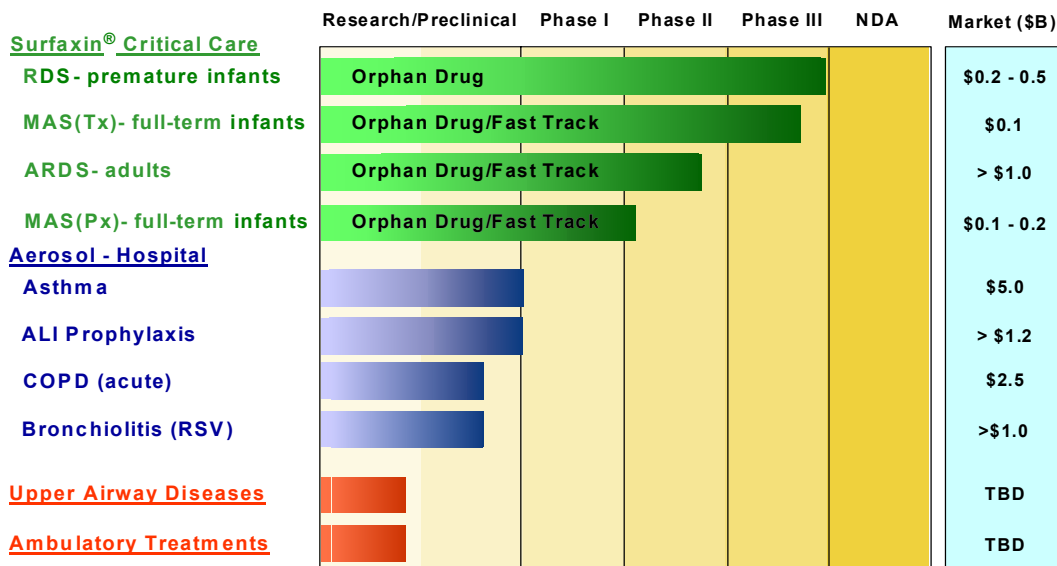
## Surfactant Replacement Therapy for Respiratory Medicine

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including respiratory distress syndromes (RDS & ARDS), Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disease (COPD), and upper airway disorders.

**DSCO is the only company with a surfactant technology platform engineered to mimic the essential properties of human lung surfactant. Discovery believes that through its surfactant technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for hospitalized and ambulatory patients.**

**Surfactants are produced naturally in the lungs and are essential for breathing.** They are crucial to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. Should surfactants degrade or be destroyed, the air sacs in the lungs collapse, airflow becomes restricted, and the lungs do not absorb sufficient oxygen.

### EXTENSIVE RESPIRATORY PIPELINE WITH SIGNIFICANT MARKET OPPORTUNITY



### COMMON STOCK OVERVIEW

|                                    |                 |  |
|------------------------------------|-----------------|--|
| 52-Wk Range                        | \$1.32 - \$8.50 | <b>Institutional Ownership</b><br>Orbimed Advisors, Inc., Heartland Value Fund, Safeco Asset Mgt., Laboratorios del Dr. Esteve, BioAsia, Special Situations, Quintiles Transnational, Putnam Investment Mgt., Quaker BioVentures, Oppenheimer Mutual Funds<br><b>Analyst Coverage</b><br>Gerard Klauer Mattison, Fulcrum Global Partners, Jesup & Lamont, Biotech Monthly, InvestBio, BI Research<br>[Discovery does not endorse any such third party materials] |
| Recent Price as of 8/12/03         | \$7.50          |  |
| Shares Outstanding                 | 41.2 MM         |  |
| Shares Outstanding (fully Diluted) | 50 MM           |  |
| Market Cap                         | \$309 MM        |  |
| Year 2002 Loss                     | \$17.4 MM       |  |
| Financial Resources (6/30/03)      | \$52.2 MM       |  |

## INVESTMENT HIGHLIGHTS

**Surfaxin<sup>®</sup>**, our lead product, is an engineered lung surfactant that is designed to precisely mimic the essential properties of human surfactant - addressing critical care indications where there are few or no therapies available. Currently in Phase 3 clinical trials for RDS in premature infants, a Phase 3 clinical trial for MAS in full-term infants, and a Phase 2 clinical trial for ARDS in adults. *The market opportunity for Surfaxin exceeds \$1.5 billion.* DSCO reported in June 2003 favorable results from its RDS supportive Phase 3 non-inferiority trial comparing Surfaxin to the leading approved animal-derived surfactant. **Results for its Phase 3 pivotal RDS trial is expected in Q4 2003 and Q2 2004 for its Phase 2b ARDS trial.**

**DSCO has evolved Surfactant Replacement Therapy by successfully developing an inhalable aerosol formulation of engineered lung surfactant with the potential to treat respiratory conditions** including asthma, ALI, COPD, and upper airway diseases. The market opportunity will initially focus on hospitalized or emergency room patients and the opportunity exceeds *\$6.0 billion.* **DSCO is positioned to enter Phase 1b / 2a clinical trials for asthma in late 2003 or early 2004 and Acute Lung Injury in early 2004.**

**Developing a commercial infrastructure to market Surfaxin** - DSCO created strategic alliances with Quintiles to develop a sales & marketing capability to commercialize Surfaxin for neonatal indications in the United States, and with Esteve for the development and commercialization of Surfaxin throughout Europe and Latin America. **DSCO plans to enter into additional strategic alliances for the broad applications and potential of its aerosol programs.**

## DISCOVERY LEADS IN SURFACTANT REPLACEMENT THERAPY

### Existing Surfactant Treatments are Limited

- There is significant scientific literature supporting the use of surfactants for respiratory diseases. Current products from animal-derived sources were FDA approved in the 1990's for Respiratory Distress Syndrome in premature infants, however limited product availability, costs and other drawbacks of these animal-derived products restrict market expansion in, and development beyond RDS.

### The Future of Surfactant Replacement Therapy

- DSCO's surfactant technology produces an engineered version of natural human lung surfactant and contains a peptide, sinapultide, that is designed to precisely mimic the essential human lung surfactant protein B (SP-B). This technology was developed by The Scripps Research Institute and Johnson & Johnson. DSCO acquired the exclusive worldwide rights in 1996. Numerous patents are issued or pending. There is a large body of scientific publications and clinical data supporting the safety and pharmacology of DSCO's surfactant technology.
- DSCO's engineered surfactants can be manufactured economically, in sufficient quantities and in exact and pharmaceutical grade quality without the risk of animal-borne diseases. In addition, DSCO's surfactants can be precisely formulated as inhalable aerosols (liquid or dry powder).
- Other than the animal-derived products, DSCO is presently unaware of other significant competing surfactant programs.



## **CURRENT CLINICAL PROGRAMS**

### **Surfaxin for Respiratory Distress Syndrome (RDS) in Premature Infants**

Premature infants born prior to 32 weeks of gestation have not fully developed a natural lung surfactant and need treatment to sustain life, often requiring mechanical ventilation. This affects approximately 2 million babies worldwide with about 270,000 cases in the developed world. Due to limitations with the animal-derived products, approximately 100,000 receive therapy worldwide, and thus the market has been limited to \$200 million. In June 2003, DSCO completed a supportive Phase 3 non-inferiority trial comparing Surfaxin to Curosurf, a pig-derived surfactant and the market leader in Europe, with successful results indicating equivalence to Curosurf (refer to Recent Developments). Surfaxin is currently in a pivotal Phase 3 clinical trial to demonstrate the superiority of Surfaxin over the only commercially available synthetic surfactant and has a reference arm comparing Surfaxin to a bovine (cow) derived surfactant. Surfaxin has received FDA Orphan Drug Status for this indication. DSCO believes Surfaxin has the ability to improve therapy and expand the market by reaching infants who do not have access today. The results from the pivotal Phase 3 trial are expected in Q4 2003.

### **Surfaxin for Acute Respiratory Distress Syndrome (ARDS) in Adults**

ARDS is a life-threatening disorder for which no approved therapies exist anywhere in the world. ARDS is characterized by an excess of fluid in the lungs, decreased oxygen levels, and the destruction of surfactants present in lung tissue. These conditions are caused by events including pneumonia, septic shock, aspiration of gastric contents, smoke inhalation, near drowning, industrial accidents and other traumas. There are an estimated 300,000 to 500,000 ARDS patients each year in the U.S. and Europe. The mortality rate ranges from 30% to 50%. Current standard of care includes placing patients on mechanical ventilators in intensive care units at a cost exceeding \$8,500 per day for an estimated average of 21-28 days. The market potential for an effective therapy is estimated to be between \$1-3 billion annually. DSCO is applying its "Surfaxin Lung Wash", which is intended to cleanse and remove inflammatory substances and debris from the lungs, while leaving amounts of Surfaxin behind to help re-establish the lungs' capacity to absorb oxygen. The objective is to restore functional surfactant levels and to allow critically ill patients to be removed from mechanical ventilation. In Q3 2002, DSCO announced very encouraging results from Part A of its Phase 2 clinical trial. Part B of this Phase 2 trial is expected to be completed in the second quarter of 2004. Surfaxin has been granted FDA Fast Track designation and both the FDA and the EU's EMEA have granted Orphan Drug Designation for this indication.

### **Surfaxin for Meconium Aspiration Syndrome (MAS) in Full-term Infants**

MAS results when full-term babies pass their first bowel movement in the womb and aspirate the meconium into their lungs. MAS infants require costly mechanical ventilation and may suffer debilitating lung conditions and other complications. There are currently no approved therapies in the world. The FDA and the EU's EMEA have both granted Surfaxin Orphan Drug Designation for this indication. Phase 3 clinical trial is expected to be completed in 2004. A clinical program for Surfaxin as a prophylactic entered Phase 2 trials in Q2 2003.

### **Inhalable Aerosol Surfactant - Severe Asthma**

Asthma is a common disease characterized by sudden, recurrent constriction of the airways and chronic inflammation of the lungs. Several studies have shown that surfactant damage and dysfunction is a significant component of asthma -- during an asthma attack, there is a surfactant dysfunction in the airways of the deep lung that causes airway obstruction. Surfactant Replacement Therapy has the potential to relieve the obstruction in the airways associated with asthma. In the United States alone, there are roughly one million hospital outpatient visits and 1.8 million emergency room visits each year due to asthma. DSCO is positioned to enter Phase 1b / 2a clinical trials in late 2003 / early 2004.

### **Inhalable Aerosol Surfactant - Acute Lung Injury (ALI)**

Acute Lung Injury is a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs' natural surfactant layer. The most serious manifestation of ALI/ARDS. There is an estimated one million hospitalized patients a year at risk in the United States for Acute Lung Injury. There are currently no approved therapies. An aerosolized Surfactant Replacement Therapy may be effective as a preventive measure for patients at risk for ALI by providing a functioning surfactant to act as an anti-inflammatory and to maintain proper lung function. DSCO is positioned to enter Phase 1b / 2a clinical trials in early 2004.

## RECENT DEVELOPMENTS

- **August 2003 – DSCO implements initial phase of long-term manufacturing strategy** – Surfaxin manufacturing capabilities were transferred to Laureate Pharma, L.P., which will become the Company's new contract manufacturer. Laureate Pharma has cGMP-compliant manufacturing facilities in Princeton and Totowa, New Jersey as well as a successful history of producing sterile pharmaceutical and biopharmaceutical products.
- **June 2003 – DSCO completes \$27.5 million private placement financing** - DSCO sold approximately 5.0 million shares at a price of \$5.50 per share. The financing included Quaker BioVentures, Inc, Special Situations Funds, PharmaBio Development, Inc., Laboratorios del Dr. Esteve S.A., and other selected investors including a well-known mutual fund.
- **June 2003 – DSCO announces positive results from its supportive Phase 3 multinational clinical trial of Surfaxin for Respiratory Distress Syndrome (RDS) in premature infants** - This supportive study was designed as a non-inferiority trial comparing Surfaxin to Curosurf, a pig-lung extract. Curosurf is believed by many of the world's leading neonatologists to be the best surfactant currently approved. Based on preliminary analysis of the data, the following encouraging key results were reported:
  - Patients alive and without chronic lung disease or bronchopulmonary dysplasia (BPD) at 28 days of age - Surfaxin was statistically equivalent to Curosurf and demonstrated an approximate 14% relative difference in favor of Surfaxin for this endpoint.
  - All cause mortality at 28 days of age - The data demonstrated an approximate 27% relative difference in favor of Surfaxin for this endpoint.
- **May 2003 – DSCO's CEO testifies before U.S. Congressional Subcommittee regarding the possible application of Surfactant Replacement Therapy to address Severe Acute Respiratory Syndrome (SARS)** - Dr. Capetola discussed SARS as a highly contagious viral infection that in severe cases progresses to life-threatening ALI/ARDS. Discovery's Surfactant Replacement Therapy has the potential to play an important role in addressing the SARS crisis by maintaining or restoring proper lung function.
- **April 2003 – DSCO develops its surfactant as an inhalable aerosol that retains critical therapeutic properties** – DSCO's surfactant was aerosolized as an inhalable liquid formulation that exhibited the following: 1) retention of essential pharmacological properties of a functioning surfactant including; surface-tension lowering ability necessary to restore lung function and keep airways open and expanded, 2) particle size and distribution suitable for deposition in lungs, 3) delivery rates for therapeutic dosing in an appropriate time period, and 4) reproducible aerosol output.
- **July 2002 – Successful completion of dose-ranging stage of Phase 2 ARDS trial** – The Independent Safety Review Committee unanimously determined that the trial procedure is generally safe and tolerable. Although the number of treated patients was small (22 patients), the results were encouraging with the highest dosing groups proving most effective, and reporting significant reductions in mortality as well as time on mechanical ventilation versus standard of care.

## INVESTOR CONTACTS

|                     |  |                       |
|---------------------|--|-----------------------|
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*Except for the historical statements contained in this Fact Sheet, statements that relate to future plans, events or performance are forward-looking and involve risks and uncertainties that could cause actual results, events or performance to differ materially from those anticipated in such forward-looking statements. Although the Company believes that the forward-looking statements contained herein are reasonable, it can give no assurance that the Company's expectations are correct. All forward-looking statements are expressly qualified in their entirety by this Cautionary Statement and the risks and other factors detailed in the Company's reports with the SEC.*