



Discovery Labs and Esteve Restructure Their Strategic Alliance

Discovery regains rights in key European markets and Latin America

Esteve broadens access to SRT products and will commercialize in key Southern European markets.

Warrington, PA — December 7, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO) and Laboratorios del Dr. Esteve S.A. (Esteve) have restructured their strategic alliance for the development, marketing and sales of Discovery's products in Europe and Latin America. Under the revised collaboration, Discovery has regained full commercialization rights in key European markets, Central America and South America for its Surfactant Replacement Therapies (SRT), including Surfaxin[®] for Respiratory Distress Syndrome (RDS) in premature infants and Acute Respiratory Distress Syndrome (ARDS) in adults. Esteve will focus on the key Southern European markets, and now has development and marketing rights to a broader portfolio of Discovery's potential SRT products. This restructured collaboration supersedes the existing sublicense and supply agreements between Discovery and Esteve entered into in March 2002.

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

On December 3, 2004 Discovery and Esteve agreed to restructure their business arrangements by entering into amended collaboration, supply and common stock agreements. The key arrangements and terms are as follows:

Discovery regained full commercialization rights for its SRT products including Surfaxin, for RDS and ARDS in Europe (excluding Southern Europe which is retained by Esteve, as mentioned below), Central America, and South America. In connection with regaining the commercial rights for these markets:

- Discovery issued 500,000 shares of its common stock to Esteve at no cost to Esteve.
- Discovery will pay Esteve 10% of cash up-front and milestone fees that Discovery may receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain of its SRT products in the territory previously licensed to Esteve. The total amount of such cash payments by Discovery to Esteve shall not exceed \$20 million.

Esteve will retain full commercialization rights in its core operating markets in Southern Europe, principally Spain, Italy, Portugal and Greece. Discovery has granted Esteve rights to additional potential SRT products in Discovery's pipeline to now include (i) Discovery's NICU SRT pipeline including Surfaxin for RDS and Bronchopulmonary Dysplasia (BPD),

SRT for Meconium Aspiration Syndrome (MAS), and aerosol formulations for Neonatal Respiratory Failures administered through nasal continuous positive airway pressure (nasal CPAP); and (ii) Discovery's Hospital SRT pipeline including Surfaxin for ARDS, and aerosol formulations for Acute Lung Injury (ALI), Asthma, and Chronic Obstructive Pulmonary Disease (COPD).

- Esteve will pay Discovery a transfer price on sales of Surfaxin and other SRT products. The transfer prices are increased from those provided for in the previous collaborative agreement. Discovery will be responsible for the manufacture and supply of all products, including Surfaxin and Esteve will be responsible for all sales and marketing in the revised territory.
- Esteve shall pay to Discovery specified cash fees based upon achieving certain milestones, primarily upon obtaining EMEA regulatory approvals for the covered SRT products.
- Esteve will contribute to Phase 3 clinical trials for the covered SRT products, by conducting and funding development performed in Southern Europe.

Discovery expects to take a charge against earnings equal to approximately \$4.2 million for the fourth quarter of 2004, primarily in connection with the issuance of such shares and other related matters associated with the restructured strategic alliance.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, "We have enjoyed a long-standing relationship with Esteve. They remain a top shareholder with approximately 2.6 million shares and Dr. Antoni Esteve is a valuable member of our board of directors. Together we have approached this decision to redefine our alliance with the intent to optimize the medical and economic value of the Surfaxin brand. Esteve now has access to the full complement of our present NICU and Hospital SRT pipeline, and can focus their efforts in their core commercial markets. Discovery may now pursue additional partners with commercial strength in Northern and Eastern Europe. Given the robustness of the Surfaxin RDS data, and encouraging ARDS Phase 2 data, we believe we are well positioned to secure additional collaborative commercialization opportunities."

Dr. Antoni Esteve, Director of Scientific and Commercial Operations at Esteve, commented, "We believe that Discovery's SRT has the promise to dramatically improve respiratory medicine in the next decade, beginning with the potential launch of Surfaxin for RDS. The redefined arrangement with Discovery will allow Esteve to reinforce our respiratory pipeline by having access to a wider SRT product platform and to focus our development and marketing efforts in our core markets, Southern Europe, while facilitating Discovery's implementation of its global SRT strategy."

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.

About Laboratorios del Dr. Esteve

Esteve is one of the largest pharmaceutical-chemical corporations in Southern Europe, with an international presence through subsidiaries in Italy and Portugal and worldwide licensees and distributors. Since 1960, Esteve has established strategic alliances with multinational pharmaceutical-chemical companies to market their products in Southern Europe. Esteve has established its own successful research and development capabilities, developing new chemical entities and manufacturing active pharmaceutical ingredients with its research products marketed in over 90 countries.

More information about Esteve is available at www.esteve.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 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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