



DISCOVERY LABORATORIES, INC.

Discovery Laboratories Files Shelf Registration Statement

Doylestown, PA — December 19, 2003 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases, has filed a Form S-3 shelf registration statement with the Securities and Exchange Commission (SEC) for the proposed offering from time to time of up to 6.5 million shares of its common stock.

Discovery has no immediate plans to sell its securities under this shelf registration. Once this registration statement is declared effective by the SEC, the Company will be able to issue these securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

A registration statement relating to the securities listed in the shelf registration statement has been filed with the SEC but has not yet become effective. These securities may not be sold nor may offers to buy be accepted before the registration statement becomes effective. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

About Discovery Laboratories

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes in infants and adults, Acute Lung Injury, asthma, Chronic Obstructive Pulmonary Disease and upper airway disorders. Surfactants are compositions produced naturally in the lungs and essential for breathing. Discovery's technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of 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 critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery recently completed Phase 3 trials of Surfaxin[®], the Company's lead product, for the treatment of Respiratory Distress Syndrome in premature infants and is preparing to file new drug applications with the United States Food and Drug Administration and other regulatory authorities in the rest of the world. Discovery's Surfactant Replacement Therapy is also in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, a Phase 3 and a Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants, and a Phase 1b clinical trial for asthma.

More information about Discovery Laboratories 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), risks relating to the progress of the Company's research and development, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with sufficient amounts of drug products for completion of any of the Company's clinical studies, other risks relating to the lack of sufficient 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-KSB, 8-K, 10-Q and 10-QSB, and amendments thereto.

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