

## **Discovery Labs' Response to Surfaxin Approvable Letter Deemed Complete by FDA**

WARRINGTON, Pa., Nov. 16, 2007 (PRIME NEWSWIRE) -- Discovery Laboratories, Inc. (Nasdaq:DSCO) today announced that the U.S. Food and Drug Administration (FDA) has accepted Discovery Labs' submission of November 1, 2007 as a complete response to the April 2006 Approvable Letter for Surfaxin(r) (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has established May 1, 2008 as its target date to complete its review of the Surfaxin New Drug Application (NDA).

The Approvable Letter for Surfaxin did not require any additional clinical trials, but primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the Surfaxin NDA, predominately involving drug product specifications and stability, analytical methods and related controls. In December 2006, Discovery Labs met with the FDA to clarify certain of the key CMC matters identified in the Approvable Letter and obtain guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin. At that meeting, Discovery Labs also presented information regarding its comprehensive investigation into and remediation of the April 2006 process validation stability failure.

Based on the guidance obtained at the FDA meeting, Discovery Labs filed its formal response which included six-month stability data on new Surfaxin process validation batches and additional data compiled from certain projects intended to address the outstanding CMC issues identified in the Approvable Letter.

### About Surfaxin(r)

Surfaxin is a precision-engineered version of natural human lung surfactant and contains Discovery Labs' novel KL-4 peptide. Surfaxin, administered as a liquid-instillate, represents a potential alternative to the commercially available animal-derived surfactants. Data from Discovery Labs' pivotal, multinational SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS and results in improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. The SELECT and STAR (a supportive Phase 3 study) trials, as well as a pooled analysis of the Phase 3 studies, have been presented at several international medical meetings and the results from the two studies were published in *Pediatrics*. In addition, top-line results from Discovery Labs' Phase 2 clinical trial for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) suggested that infants treated with up to five incremental standard doses of Surfaxin tended to have a lower incidence of death or BPD, a higher survival rate through 36 weeks post-menstrual age, and fewer days on mechanical ventilation. Discovery Labs recently initiated a Phase 2 clinical trial evaluating the use of Surfaxin in children up to two years of age suffering from Acute Respiratory Failure (ARF). This new trial will explore the expanded application of surfactant therapy to pediatric critical care medicine.

**DISCLOSURE NOTICE:** The information in this press release includes certain "forward-looking" statements relating to, among other things, the remaining steps necessary for FDA approval of Surfaxin for the prevention of RDS in premature infants, including information included in Discovery Labs' formal response to the Approvable Letter. Although Discovery Labs is encouraged by the progress that it believes it has made to date in filing its formal response to the Approvable Letter and in achieving six months stability with its new process validation batches, gaining approval of Surfaxin involves ongoing activities, the final results of which could vary materially from Discovery Labs' expectations and results obtained to date. Discovery Labs currently believes that it will succeed in gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants within the timeframe indicated above; however, these activities are subject to a variety of risks, including but not limited to risks that (i) Discovery Labs may not have succeeded in adequately responding to the matters raised in the Approvable Letter, (ii) the new process validation batches may after the 6-month stability period fail to meet designated stability or other release parameters, and (iii) Discovery Labs may identify unforeseen problems that have not yet been discovered. Any failure to provide information required by the FDA in our

response to the Approvable Letter could result in significant delays or additional requirements and could potentially prevent the approval of Surfaxin or other Discovery Labs' products.

#### About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory diseases.

Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery Labs' lead product candidate, Surfaxin(r), is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. Surfaxin is also being developed for other neonatal and pediatric indications. Aerosurf, Discovery Labs' aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at [www.Discoverylabs.com](http://www.Discoverylabs.com).

To the extent that statements in this press release are not strictly historical, 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 risk factors which could affect Discovery Labs' actual results and could cause results to differ from those contained in these forward-looking statements are the risks that: Discovery Labs may be unable to profitably develop and market its products; financial market conditions may change; Discovery Labs may not be able to raise additional capital or enter into additional collaboration agreements; Discovery Labs may not be able to attract or retain qualified personnel or timely provide for successful sales and marketing activities; Discovery Labs' research and development efforts may not progress; Discovery Labs may not be successful in the FDA or other regulatory agency review process generally, including that such regulatory authority will not approve the marketing and sale of a drug product even after accepting an application or may withhold, delay and/or limit marketing a drug product by indication or impose other label limitations; Discovery Labs' recently-submitted response to the Approvable Letter may not satisfy the FDA; Discovery Labs or its third party manufacturers and development partners may be unable to manufacture or provide adequate supplies of drug substances and expertise to allow for completion of any of Discovery Labs' clinical studies; Discovery Labs and its collaborators may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs drug products with innovative aerosolization technologies; Discovery Labs may not be able to successfully manufacture its drug product candidates; Discovery Labs' significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and efforts to gain regulatory approval for any products that it may develop (independently or in connection with collaboration arrangements) may not succeed; other companies may develop competing therapies and/or technologies; reimbursement and health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in securities, product liability and other litigation. The foregoing risks and others are further described in Discovery Labs 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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