



Discovery Labs Provides Update on Progress for Surfaxin[®] for RDS

Conference Call Today at 10:00 A.M.

Warrington, PA — August 2, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today reports progress in addressing previously-announced manufacturing and stability issues and the April 2006 FDA Approvable Letter (Approvable Letter), which focused on the Chemistry, Manufacturing and Controls (CMC) section of the New Drug Application (NDA) for Surfaxin[®] (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Discovery Labs remains on track to file its formal response to the Approvable Letter in the October 2007 timeframe, followed by an anticipated six-month review cycle by the FDA for potential approval of the Surfaxin NDA.

April 2006 Surfaxin Process Validation Stability Failure

Immediately following the April 2006 process validation stability failure, Discovery Labs conducted a comprehensive investigation into the stability failure, including identifying a most probable root cause, and remediated by executing a comprehensive corrective action and preventative action (CAPA) plan. As part of the investigation, Discovery Labs manufactured a series of investigational batches that supported the manufacture of three new process validation batches. These investigational batches are monitored using Discovery's most predictive stability-indicating method and continue to demonstrate acceptable stability, with the earliest manufactured batches continuing to demonstrate acceptable stability through twelve months, and the most-recently manufactured, through six months.

In February 2007, Discovery Labs completed the manufacture of the three new Surfaxin process validation batches that are a requirement for approval of the Surfaxin NDA. These process validation batches are subjected to comprehensive stability testing on pre-specified testing dates, in accordance with an established protocol that complies with ICH guidelines. Under the comprehensive testing protocol, these process validation batches have demonstrated acceptable stability through three months and continue to be monitored. The process validation batches must demonstrate acceptable stability through six-months under the comprehensive testing protocol before Discovery Labs can file its formal response to the Approvable Letter. Discovery Labs anticipates that six-month stability data will be available in October for inclusion in the formal response.

The new Surfaxin process validation batches were manufactured consistent with guidance obtained from the FDA at the December 2006 meeting. At that meeting, Discovery Labs presented information to the FDA regarding its comprehensive investigation and remediation of the April 2006 process validation stability failure. Included was information associated with the manufacture of the series of investigational batches, using a process consistent with that used to produce Surfaxin for Discovery Labs' successful RDS clinical trials. Discovery Labs applied the manufacturing process used to produce the investigational batches to produce the three new process validation batches.

April 2006 FDA Approvable Letter - Chemistry, Manufacturing and Controls

Discovery received an Approvable Letter for Surfaxin in April 2006 that primarily focused on the CMC section of the Surfaxin NDA. The Approvable Letter did not require any additional clinical trials, but requested additional information predominantly involving drug product specifications and stability, analytical methods and related controls. The CMC section of an NDA contains information to demonstrate that the drug product can be manufactured consistently to meet appropriate product quality requirements.

In December 2006, Discovery Labs met with the FDA to gain the clarity necessary to address key remaining CMC issues identified in the Approvable Letter. The FDA's guidance provided a defined pathway for Discovery Labs to generate additional data from selected experiments that are essential for approval of Surfaxin for the prevention of RDS in premature infants.

Discovery Labs believes it has made significant progress in addressing the outstanding issues identified in the Approvable Letter and is currently focused on completing the experiments, and compiling and analyzing the data for submission to the FDA. Discovery Labs believes that its progress to date supports the filing of the formal response to the Approvable Letter in the October 2007 timeframe.

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 being prepared for inclusion in Discovery Labs’ formal response to the Approvable Letter and the potential results of both Discovery Labs’ comprehensive manufacturing investigation and the ongoing release and stability testing of the investigational batches and the new process validation batches. Although Discovery Labs is encouraged by the progress that it believes it has made to date, the development of data and other relevant information for the formal response to the Approvable Letter, including the release and stability testing of the investigational batches and the new process validation batches, are ongoing and the final results of these efforts could vary materially from the observations and results obtained to date. Discovery Labs currently believes that it will succeed in submitting its formal response to the Approvable Letter, with six months of successful stability data for the new process validation batches, within the timeframe indicated above, subject, however, to a variety of risks, including that (i) Discovery Labs may not succeed in completing its experiments or developing the data and other information necessary for the formal response, (ii) the new process validation batches may in the future fail to meet designated stability or other release parameters, and (iii) Discovery Labs may identify unforeseen problems that have not yet been discovered. The reader of this release should understand that the failure to develop all necessary information required to respond to the Approvable Letter, including at least six months of stability data for the new process validation batches, could result in significant delays or additional requirements and potentially prevent the approval of Surfaxin or other Discovery Labs products.

Conference Call Details

Discovery Labs will hold a conference call today at 10:00 AM EDT to further discuss 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 through a live broadcast on the Internet at

<http://investor.shareholder.com/media/eventdetail.cfm?mediaid=26687&c=DSCO&mediakey=50596D7D4BE16CECBA5B9FD9E893B75A&e=0> and www.discoverylabs.com. The replay number to hear the conference call is 800-642-1687 or 706-645-9291. The passcode is 10288727.

About Surfaxin

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 Phase 3 analysis, 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 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.

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[®], 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.

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 factors which could affect Discovery Labs actual results and could cause results to differ from those contained in these forward-looking statements are the risk that Discovery Labs may not profitably develop and market its products, the risk that financial market conditions may change, the risk that Discovery Labs will not be able to raise additional capital or enter into additional collaboration agreements, the risk that Discovery Labs will not be able to attract or retain qualified personnel or timely provide for a successful sales and marketing organization, risks relating to the progress of Discovery Labs research and development, risks 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 acceptance of an application or that approval by such

regulatory agency may be withheld, delayed and/or limited by indications or other label limitations, risks that the Chemical, Manufacturing and Controls section of Discovery Labs New Drug Application will not satisfy the FDA, risks relating to the ability of Discovery Labs or Discovery Labs third party manufacturers and development partners to manufacture or provide Discovery Labs with adequate supplies of drug substances and expertise for completion of any of Discovery Labs clinical studies, risks related to the ability of Discovery Labs and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery Labs drug products with innovative aerosolization technologies, risks relating to drug manufacturing by Discovery Labs, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval process for any products that Discovery Labs may develop independently or with Discovery Labs collaboration arrangements, risks relating to the development by other companies of competing therapies and/or technologies, risks relating to reimbursement and health care reform, and risks relating to securities, product liability and other litigation. 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 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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